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REPORT

of the

ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE

October 7, 1985

Presented to
The Honourable D. J. Russell
Minister of Hospitals and Medical Care
Government of Alberta

October 7, 1985

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ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE

October 7, 1985

Submitted by

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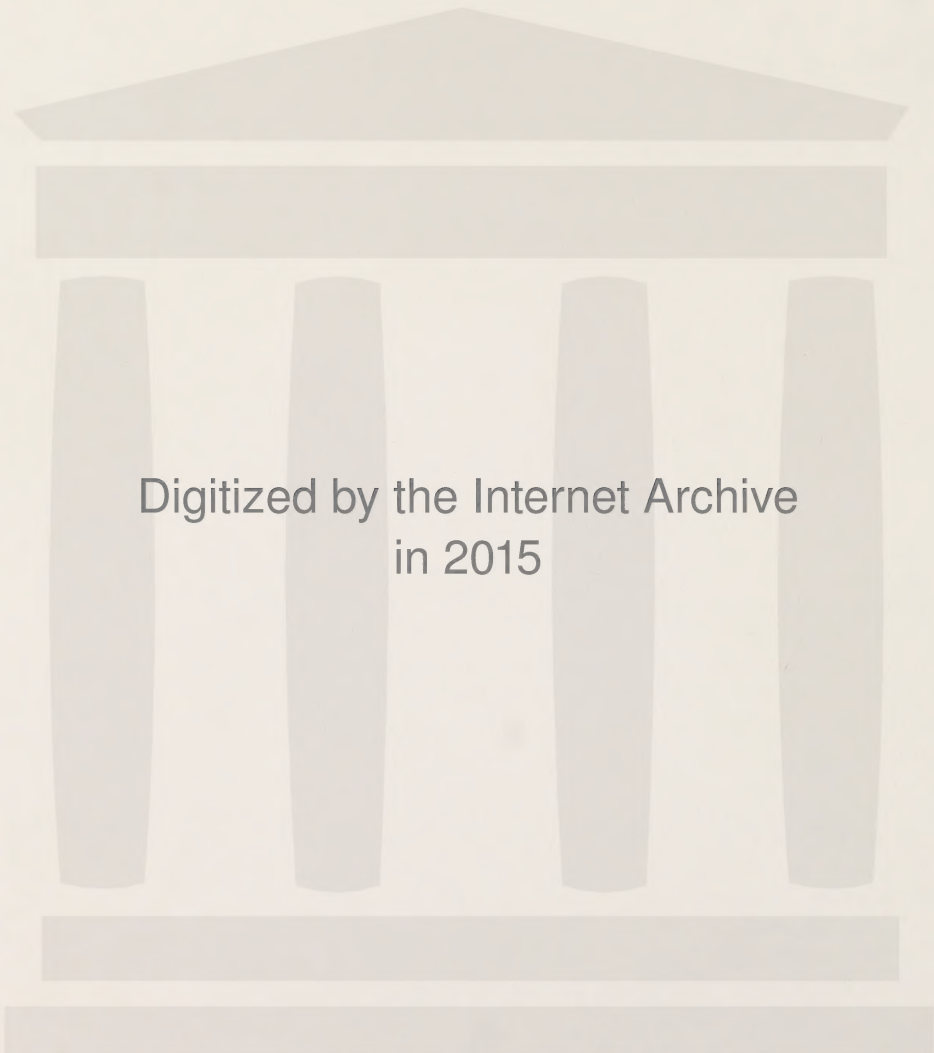
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October 7, 1985

The Honourable D. J. Russell
Minister of Hospitals and Medical Care
Room 420 Legislature Building
Edmonton, Alberta

Dear Mr. Russell:

Following the directives established by Ministerial Order No. 33.82, September 10, 1982, we have now completed our study of the transplantation of human organs and tissue in Alberta.

In fulfilling our mandate as outlined in the Ministerial Order, the Task Force was delighted with the response from the groups and individuals in Alberta with an interest in solving the problems of transplantation and by their genuine committment to assisting the Task Force in this process.

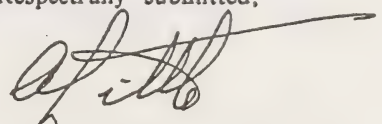
It is apparent that transplantation is one area in which advances in medical science are quickly applied to a clinical situation. This rapid clinical application with its recent overwhelming success has in turn created social and economic problems for those working in the area of organ transplantation.

The Task Force recognizes that medical science may move with amazing speed and that in the future basic medical research into the causes of disease may prevent the processes, presently treatable by transplantation. For this reason, the Task Force has sought realistic and workable solutions to today's problems.

The Task Force is pleased to report that while far short of perfect, the transplant system in Alberta is basically healthy, and trust that timely implementation of their recommendations will substantially improve the existing situation, bringing life and health to those in need.

During the past month the members of the Task Force were saddened by the untimely and tragic death of member Peter Craigie. Peter Campbell Craigie, Ph.D., Dean of Humanities and Vice-President (Academic), University of Calgary, made valuable contibutions to the debate of the Task Force and fathered and refined the concept of the Council for Transplantation. In consideration of his significant contribution to the studies of the Task Force the members dedicate this Report to his memory. His passing leaves a void that will not be easily filled.

Respectfully submitted,



Andrew Little, Chairman.

To: The Honourable D. J. Russell
Minister
Alberta Hospitals and Medical Care

The Alberta Human Tissue Procurement Task Force, established in September, 1982, herewith submits its reports and recommendations for consideration by the Minister of Hospitals and Medical Care.

Chairman:

Andrew Little

Members:

John Butt, M.D.

John M. G. Dahl

John B. Dossetor, M.D.

D.T.R. Hassard, M.D.

John Klassen, M.D.

William H. Lakey, M.D.

Joan E. Nightingale, R.N., B.B.A.

This report is dedicated to our former colleague and dear friend

DR. PETER CAMPBELL CRAIGIE

August 18, 1938
September 26, 1985

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EXECUTIVE SUMMARY

The Alberta Human Tissue Procurement Task Force was appointed by the Minister of Hospitals and Medical Care in September, 1982 to investigate transplantation in Alberta and to develop recommendations on more effective means for donation and utilization of human organs and tissue for transplant purposes within the province. The nine member Task Force consisted of physicians from the transplant centres in the province and public health professionals, as well as other interested parties. They met regularly over the course of 36 months, reviewed available and sought new information, and identified and investigated areas problematic for transplantation in Alberta. As well, the Task Force organized a major international symposium on transplantation, held May 22 to 25, 1985 at Lake Louise, at which recognised international experts presented information on the ethical and legal issues surrounding transplantation as well as the more technical concerns of organ procurement and storage. The purpose of this symposium was to distill the thoughts of the Task Force, before an informed and potentially critical audience.

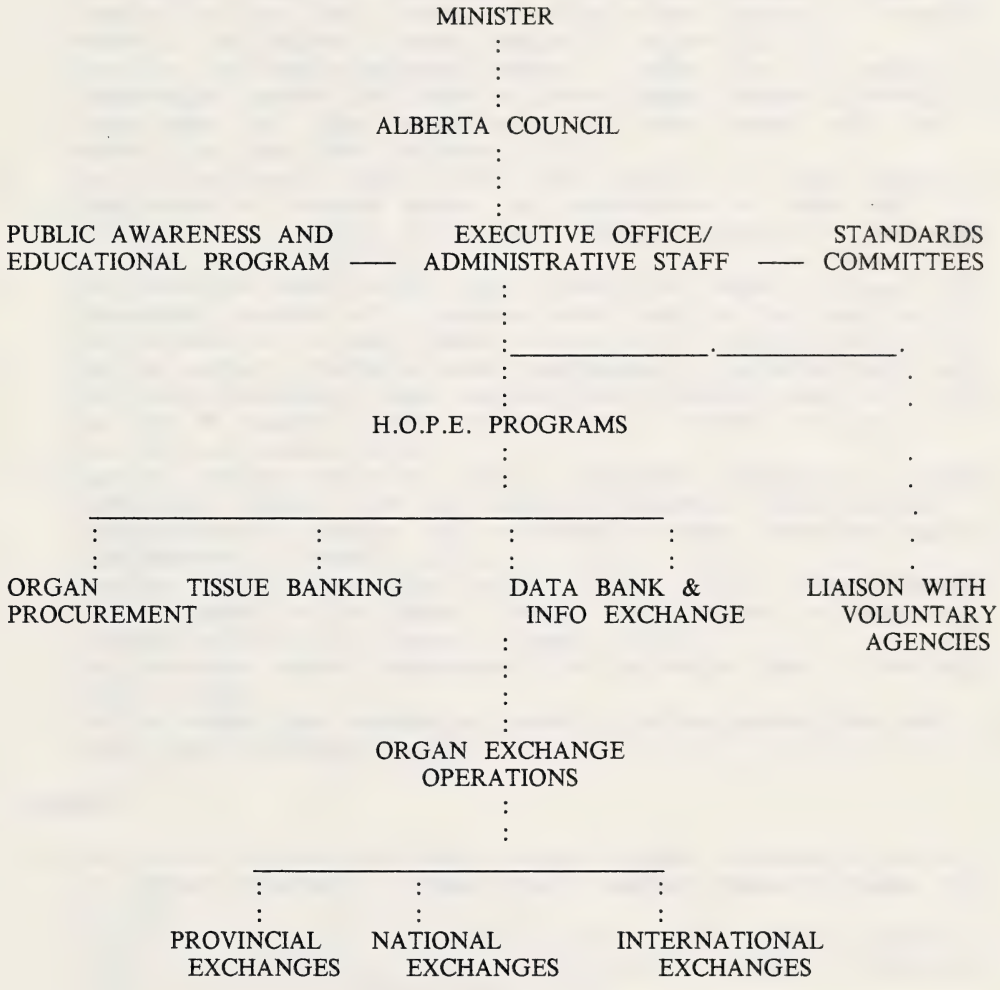
This report contains the findings and conclusions of the Task Force on the following major issues in transplantation in Alberta:

- public awareness and acceptance of the transplant process,
- barriers to transplantation within Alberta,
- standards and operating procedures related to donation, storage and utilization of human organs and tissue,
- the law related to donation, storage and utilization of human organs and tissue,
- ethical issues pertinent to the transplant process, and
- programs required to promote organ donation and use in Alberta,

The report begins with the recommendations of the Task Force and finally includes a set of appendices.

The **key recommendation** of the Task Force is to establish an umbrella organization, the Council for Transplantation, which would draw together and centrally co-ordinate all organ and tissue procurement, storage and utilization in Alberta. This crucial recommendation is developed in detail in Chapter 8 in the body of the Report and specifies the nature of the Council. The proposed Council would expand the present H.O.P.E. program, the Chief Medical Examiner's Tissue Program, and would implement the recommendations of the Task Force. The goals and responsibilities of the Council are comprehensive and are pertinent to all aspects of transplantation medicine. The Task Force is of the opinion that the proposed Council for Transplantation will be the most effective structure to implement it's recommendations, and will provide co-ordination in many growing areas. It is estimated that the cost of establishing Council and of implementing these recommendations would be approximately $1,500,000 in the first year. The structure of the proposed Council is diagrammed overleaf.

PROPOSED
COUNCIL FOR TRANSPLANTATION



Proposed function:

- promoting transplantation through extensive, continuous public and professional education, including ongoing examination of ethical and legal issues;
- facilitating procurement, utilization and exchange of organs and tissue;
- providing for storage of organs and tissue;
- establishing and recommending standards pertaining to all aspects of transplantation, within it's jurisdiction;
- providing information on availability of organs and tissue on a provincial, national, and international basis.

The Alberta Human Tissue Procurement Task Force also recommends:

Policies

- that uniform protocols be established to permit the admission, transfer and transport of brain dead donors, on organ support systems, to transplant centres for the purposes of organ donation and retrieval (p. 39);
- that the provincial government develop a policy for a) payment of transportation expenses for donors or donor organs, incurred in relation to human organ and tissue transplantation, b) related hospital costs, and c) return of the donor body for burial (p. 40);
- that, in non-transplant medical centres, strict criteria be in place regarding the identification of potential donors, the determination of brain death, and techniques for the surgical removal and subsequent perfusion and preservation of organs and tissue (p. 22);
- that technicians should receive proper training for various tissue and organ procurement procedures at a recognised centre, and that the proper guidelines and procedures are in place regarding their duties and responsibilities (p. 22);
- that the hospital or institution where transplantation is performed should ensure that proper institutional policies regarding donor selection criteria be in place and that the donor's complete medical history is available for review at the time of donor selection (p. 21);
- that the Province support the national transplantation organization, Transplant International (Canada), for the purpose of gathering official statistics on transplantation in Canada and co-ordinating public awareness regarding transplantation in Canada (p. 17);
- that the Universal Donor Card presently included on the Alberta Operator's Licence courtesy of the Solicitor General become properly authorised as a permanent addition to the Operator's Licence (p. 12);
- that physicians receive reimbursement for pre-donation care of brain-dead donors (p. 20);
- that the Alberta police communities establish a uniform province-wide policy of organ donor identification (p. 15).

Procedures

- that, on the advice of the Minister, hospital by-laws and laboratory procedures be reviewed appropriately to ensure proper, dignified disposal of human tissue (p. 50);
- that, on the advice of the Minister, each hospital's form for consent to autopsy be broadened to include authorization for retention of tissue and organs as part of the autopsy process (p. 50).

Programs

- that the Chief Medical Examiner's Program for donation of storable tissue become a permanent provincial program and that it become an integral part of the proposed Council (p. 48);
- that the Province establish a tissue bank for skin, bone and possibly corneas and that it be administered by the proposed Council for Transplantation (p.32);
- that a personnel support program be provided to the H.O.P.E. program, establishing positions for 6 nurses/surgical assistants who would be trained to assist in the operating room and in the various transplant procedures, including procurement, donation and recovery of organs and tissue (p. 44).

GLOSSARY

AIDS

Acquired immune deficiency syndrome: an infection with the virus, of the class of retroviruses, which preferentially affects the body's immune system (see Appendix R).

Brain Death

Irreversible and complete loss of function of the whole of the brain.

Brain Stem Death

Irreversible and complete cessation of all brain stem functions.

Cross matching

The process which determines whether antibodies in serum of the patient react with donor red cell antigens (or surface proteins) for red cell cross matching, or donor lymphocyte markers for white cell cross matching.

Determination of Brain Death

In patients who are comatose for reasons other than drugs, hypothermia or metabolic disease, brain death may be determined by 2 physicians acting in accordance with 'accepted medical practice' (see Appendices L.1 and L.2)

H.L.A.

Human Lymphocyte Antigens, the factors on nucleated cells of the body (thus differing from red cell antigens) which are important in 'typing' of tissues (as distinct from blood); there are over 80 HLA antigens.

H.O.P.E

H.O.P.E. is an acronym for Human Organ Procurement and Exchange, the Alberta Transplant Program.

Hypothermic Perfusion

Circulation through the organ's blood vessels of a solution which preserves function, usually a 4°C.

Non-transplant Medical Centre

Hospitals which provide donors of tissues and organs, but where transplants are not normally performed.

Pre-donation Care

Pre-donation care describes the care required to maintain a donor on organ support systems from the time of brain death to the time of donation, or determination that donation is not possible.

Storable Tissue

Human tissues which are capable of being preserved for periods longer than a few days, usually with restoration of living tissue function after transplantation.

Vascular Anastomosis

Surgical conjunction of blood vessels, to re-establish blood flow.

CHAPTER 1: INTRODUCTION

1.1 Preamble

Through technological and pharmacological advances in the past two decades it is now possible to treat a wide variety of medical problems by transplantation. At present, organ and tissue transplants involving kidneys, corneas, bone and bone joints, middle ear bones, eardrums, hearts and livers are established surgical procedures done on a routine basis. Less well known but equally accepted, are transplants involving the larynx, parathyroids, thymus glands, skin, dura mater (the hard covering of the brain) and fascia. Other transplant procedures such as pancreas cell transplants are now being evaluated clinically.

Any transplant program is limited, however, by the number of donors available and current needs for transplantable tissue far exceed supply. Because the lack of donated organs and tissue has restricted the ability of medical practitioners to treat patients effectively, the Minister of Hospitals and Medical Care appointed a Task Force to develop recommendations on the most effective means of overcoming this critical shortage. The membership of the Task Force is listed in Appendix A.

The establishment of the Alberta Human Tissue Procurement Task Force arose out of a private motion put before the Legislative Assembly by Mr. Andrew Little who was, at that time, the representative for the riding of Calgary-McCall. The motion received wide support in the house and, on September 10, 1982, the Alberta Human Tissue Procurement Task Force was established by Ministerial Order No. 33.82 under the authority of section 5 of the Department of Hospitals and Medical Care Act, R.S.A. 1980, c. H-11, as amended, by the Honourable David J. Russell, Minister of Hospitals and Medical Care. The terms of reference of the Task Force are set out in Appendix B. The first organizational meeting of the Task

Force was held October 13, 1982.

1.2 Organization of the Report

The sections and headings of this report derive from the use of the Task Force's mandate as a guideline.

1.3 Methods of Study and Scope of the Report

After an initial organization period the Task Force was able to identify a number of areas of difficulty for transplantation in Alberta. The identification of these areas and their further exploration took place in a series of interviews held by the Task Force at which selected members of the transplant-related groups within Alberta were invited for discussions with the Task Force and by other investigations of the Task Force. These investigations are presented in detail in the Appendices to the Report. Additionally, Task Force members were able to liaise with other groups active in transplantation medicine in North America to assess their progress in this area (a summary of the Ontario Task Force Report appears in Appendix G.2).

1.4 The International Symposium on Organs for Transplantation

The Task Force organised a major meeting on organ transplantation, the "International Symposium on Organs for Transplantation", held at Lake Louise, May 22-25, 1985, which provided the Task Force with expert opinion from widely respected transplant professionals. The Symposium was unique in that it was the first of its kind to examine all the facets of transplantation including the philosophical problems, the ethical and legal issues, and clinical and research aspects.

The Symposium was conceived as a means of bringing to Alberta experts in various fields related to organ and tissue procurement, including its legal and ethical aspects. The subjects were covered in a succession of five panel discussions. After the keynote speaker, Mr. Malcolm Muggeridge, (a veteran newspaperman, author, ethicist, and philosopher who is known for his forthright views on many issues) came a panel on ethics in organ procurement, followed by the legal aspects, after which came a discussion on the issues that attend procurement of those organs requiring vascular anastomosis, an area that has become more complicated recently by the need for multiorgan procurement. This was followed by a panel on those human tissues that do not require surgical anastomosis, and that are storable. On the last half day of the symposium we considered the economic aspects of organ transplantation and the role of Government and of research funding agencies such as the Alberta Heritage Foundation for Medical Research.

The Symposium was planned at a time when transplantation in Alberta consisted of programs for kidney and cornea transplantation at the Universities of Calgary and Alberta, in Edmonton, and when heart transplantation was imminent at the latter university. Transplants of joints were also being performed in Calgary by Dr. Norman Schachar and skin transplants being carried out in the Burn Units at both major cities in the Province of Alberta. Cryobiologic initiatives were taking place at both universities with plans for pancreatic islet transplants within the foreseeable future.

The Symposium enabled the Task Force to evaluate a variety of solutions to the problems of transplantation and crystallised many of it's conclusions. Papers given at the Symposium (listed in Appendix D) will be published in "Transplantation Proceedings", a scientific journal with an international distribution, in late 1985. Mr. Muggeridge's presentation was videotaped through the co-operation

of the Department of Radio and Television at the University of Alberta and by ACCESS Alberta (further details are given in Appendix E) for educational use.

CHAPTER 2: PUBLIC AWARENESS AND ACCEPTANCE OF TRANSPLANTATION

2.1 Public Opinion Poll

One of the early concerns of the Task Force was to gauge public opinion in Alberta regarding transplantation with a view to possible changes in legislation or donation procedures. In March 1983 the Task Force decided to call for written submissions from the public on donation of organs and tissue for transplantation. An advertisement was designed and it posed the following questions:

- Where do you stand on the subject of organ and tissue transplants?
- Should the decision to donate or not be mandatory or voluntary?
- Should next-of-kin have the right to alter a donor's wishes?
- Should the driver's licence donor card system be replaced by a computer bank? How should the new system operate?

The advertisement was placed in the daily, religious and ethnic newspapers published throughout the province on September 9, 1983. Many individuals responded to the newspaper advertisement and their responses were, for the most part, extremely thoughtful opinions. Appendix G.1 provides a brief synopsis of the responses received.

An analysis of the responses received revealed a significant consistency between all those individuals responding and the Task Force was able to conclude that, at present, tissue donation and transplantation is not a particularly controversial subject in Alberta. However, the majority of the respondents expressed a need for much greater public education. Several pointed out that while they were in favour of transplantation and wanted to make a post mortem donation, they simply did not know how to record their wishes.

Among suggestions for obtaining and/or recording donations were the following:

- a Universal Donor Card distributed with the Alberta Health Care card or similar document;
- advertisements soliciting donations using the Yellow Pages with space provided by Alberta Government Telephones;
- the involvement of various church groups throughout the province as vehicles for both public education and the encouragement of donations.

In general, the responses to the advertisement could be considered as unemotional or unheated except on one point -- mandatory versus voluntary donation. It was apparent that the possibility that the government might even be contemplating mandatory donation was a subject of considerable alarm. It should also be noted that the majority of respondents were of the opinion that the next-of-kin should not have the right to alter the donor's wishes.

2.2 Other Submissions to the Task Force

From time to time during their 36 month period of operation the Task Force received submissions from members of the public on various aspects of transplantation in Alberta (Appendix C, Other Submissions to the Task Force). These submissions were welcomed by the Task Force as they provided a measure of public opinion in Alberta. While the submissions discussed a range of problems there were two themes which were constantly repeated:

- education/advertising regarding organ donations and
- emphasis on the voluntary aspect of donation, with a related concern that the medical profession and government will control transplantation both from the

point of view of donors and recipients.

2.3 The Donor Card in Alberta

In response to requests from concerned citizens and the medical profession, the Alberta driver's licence which became effective April 1, 1978 included an organ donor card (the Universal Donor Card on the back of the licence) for voluntary completion by the licencee. This was authorised by s. 3(1)(b)(vii) of Alberta Regulation 123/78, a regulation under the Motor Vehicle Administration Act, which states:

"(b)Part II shall contain the following particulars of the licencee:
(vii)any special conditions and endorsements on his licence."

The Universal Donor Card is included on the back of the Alberta Operator's Licence as a courtesy of the Department of the Solicitor General. By authorizing the Universal Donor Card as a permanent addition to the Operator's Licence the Task Force is of the opinion that this measure would emphasize the government's commitment to transplantation, would provide a relatively inexpensive method of public education, and would ensure the continued existence of the donor card.

Recommendation

It is recommended that the Universal Donor Card presently included on the Alberta Operator's Licence as a courtesy of the Solicitor General become legally

authorised as a permanent addition to the Operator's Licence.

2.4 Donor Cards and Donor Registries

Although the public apparently perceives the donor card to be a central factor in the organ transplantation and procurement, and that an increase in signed donor cards would inevitably lead to increased organ donation, there are serious problems with this perception. Although many persons profess to be in favour of organ transplantation, few have signed donor cards. There is no way of knowing how many persons carry cards, or whether a given person has signed a card, unless the actual card can be found. Procedures at the scene of an accident appear to make this difficult. Even if a valid signed donor card is found, it may not be acted upon by hospital authorities, in spite of its legal status, without the approval of the donor's immediate family. However, the donor card is a vehicle for generating public awareness, and, although it may not be the best one, it is the most widely known. Even though the card may not be accepted as sufficient authority to proceed with organ donation in the absence of family approval, it is certainly persuasive evidence of the deceased's wishes.

The only jurisdiction in North America which records a person's decision to donate or not is the State of Arizona. The motor vehicle operators licence in Arizona provides a space for indication of participation in or rejection of the Arizona Anatomical Gift Act. Those responding positively (wishing to donate) are given an affidavit to swear and the sworn affidavits are kept on file at the motor vehicles branch. The affidavit is similar to the Universal Donor Card.

If a registry is not a viable solution, then access to the donor card must be through the efforts of the police and/or ambulance attendants. Discussion with

Calgary Police authorities and Mr. Bill Coghill of the Ambulance Authority indicate that both groups are aware of the problem and are interested in participating in a solution.

As part of their investigation into the barriers to transplantation within Alberta the Task Force held a meeting on June 20, 1984 on the problems of donor cards and donor registries. The Task Force invited the following speakers to present their views on this topic at that meeting:

Inspector K. Cavanaugh
Traffic Division
Calgary City Police

Mr. J. Hendriks, Director
Management Information Development
Alberta Hospitals and Medical Care

Mr. W. Coghill
Edmonton Ambulance Authority

Mrs. Anne Russell
Legislative Planning, Alberta
Social Services & Community Health

Mr. B. Gilroy, Registrar
Department of Vital Statistics

See Appendix H.1 for a summary of this information.

Possible solutions suggested to the Task Force to solve the problems associated with donor cards include:

- Legislation requiring persons to provide written evidence of their willingness or unwillingness to donate or their unwillingness to answer, prior to their being considered eligible for a driver's licence, health care benefits or some other desired government regulated benefit.
- A voluntary registry of donors in conjunction with an existing registry such as motor vehicle operators or insured persons under the Alberta Health Care Insurance Plan.
- Involving, either voluntarily or by legislation, those persons attending the scene of accidents in searching for donor cards.

2.5 Police Survey

The Task Force Studied the possible role of the police force in identifying organ donors, surveying police forces across Canada and examining their policies towards the organ donor card.

In May of 1984 a questionnaire to determine the use and effectiveness of the organ donor card was distributed in the Canadian police community. Nineteen police organizations were canvassed. The police administrators were well informed concerning organ donor programs and expressed a willingness to co-operate in further development of the programs. The questionnaire and responses appear in Appendix H.2. Identifying and drawing potential organ donors to the attention of medical personnel is a crucial first step in organ donation. Through their interviews and questionnaire the Task Force became aware that law enforcement officials are among the first persons to have contact with the potential donor. This early contact coupled with a willingness for further involvement has led to this recommendation for a systematic province-wide law enforcement policy towards identification of potential organ donors.

Recommendation

It is recommended that Alberta police organizations establish a uniform province-wide policy of organ donor identification.

2.6 Motor Vehicle Fatality Survey

The Task Force also examined motor vehicle fatalities in Alberta in 1982 to assess the impact of organ donation programs in Alberta. In 1982 in Alberta there were 518 motor vehicle fatalities, 162 of which occurred in south rural Alberta, 185

in north rural Alberta, 98 in Edmonton and 73 in Calgary.

To establish the number of fatalities which represented potential organ donors the cases were assessed using ideal criteria for organ and tissue donation which included such characteristics as age of donor and time of death. Details of this study appear in Appendix I.

The study indicated that, of 518 motor vehicle fatalities in Alberta in 1982, 77 cases would appear to have been ideal cases for organ donation, in Edmonton and Calgary. In fact organ donation occurred in only 9 cases or 11.7% of the ideal cases. It is apparent then that over 80% of possible organ donors from motor vehicle accidents are not being identified. The reasons for this loss were assessed further by the Task Force's examination of the barriers to organ procurement.

2.7 The Need for Public Education

There is a serious need for public education and awareness regarding organ and tissue donation and transplantation. Judging from the discussions and presentations to the Task Force it appears that motor vehicle fatalities constitute a very important area for obtaining donations. It also appears that the public education campaign must be extensive and continuous, and that is should probably be a multiple approach. Ideally, this should occur during times of good health with information made available in a variety of ways including:

1. media coverage of all fields of transplantation, including the development of new techniques;
2. through voluntary organizations;
3. donor cards on drivers' licences;
4. pamphlets in hospitals wards, admitting offices, funeral homes; and

5. continuing education in schools and universities.

Recommendation

It is recommended that the Province support the national transplantation organization, Transplant International (Canada), for the purpose of gathering official statistics on transplantation in Canada and co-ordinating public awareness regarding transplantation in Canada.

CHAPTER 3: BARRIERS TO OBTAINING ORGANS AND TISSUES FOR TRANSPLANTATION WITHIN ALBERTA

3.1 Barriers to Transplantation Within the Medical Profession

The most significant barrier to obtaining organs and tissue for transplantion is thought to lie within the medical profession itself. For whatever reason, medical staff appear reluctant to counsel organ donation. This experience is not unique to Alberta[1] alone, it has also been reported in the Netherlands,[2] West Germany,[3] and Argentina.[4]

The cause of the reluctance of medical staff to initiate a discussion on donation is difficult to understand at first glance since personal communication received by the Task Force from the H.O.P.E. Transplant Co-ordinators and the Medical Examiners indicates that donor families are not generally resistant nor offended by the suggestion of organ donation, and that the family may be comforted by the mitigation of their personal tragedy. Even if they refuse, they are not abusive towards those who ask.

The Task Force was assisted with their study of this area by representatives of the following groups: College of Physicians and Surgeons and the Alberta Medical Association, representatives for critical care physicians, representatives for emergency room physicians, representatives for neurosurgeons, Alberta Association of Registered Nurses, representatives from Intensive Care Unit nurses, neurological Intensive Care Unit nurses, emergency room nurses, and one or more Medical Directors from major hospitals.

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[1]McMaster P, *Transplantation Proc.*, XVI(1), February 1984, 220.
[2]Van der Vliet JA *et al.*, *Transplantation Proc.*, XVI(1), February 1984, 191.
[3]Schulz C *et al.*, *Transplantation Proc.*, XVI(1), February 1984, 196.
[4]Cantarovich F *et al.*, *Transplantation Proc.*, XVI(1), February 1984, 193.

A number of questions were directed towards the appropriate group to assist them in formulating their viewpoint, these and a summary of the testimony presented appears in Appendices K.1 and K.2.

3.2 Donor Identification

The suggestion that physicians who discuss organ donations with donor families receive monetary compensation is controversial. Personal communication from several physicians indicates that some believe monetary compensation in such circumstances is repugnant and unethical, while others believe that such compensation is no different from any other type of counselling which physicians regularly perform and are compensated for. Every physician the Task Force has spoken to on the subject of monetary compensation for organ donor counselling thought that monetary incentives, or the removal of disincentives, would probably increase the number of organ donor referrals.

It is widely held that constant, positive contact between procurement agencies and medical staff results in increased organ donations. Encouragement coupled with education, commitment by hospital administration and monetary compensation for organ donation counselling by physicians might well lead to the eventual reduction of unacceptably long transplant waiting lists.

The Task Force considered the question of professional fees for donor identification and counselling of families of potential donors, but there is no recommendation for such fees at this time.

3.3 Pre-Donation Care of Brain Dead Donors

Special efforts must be made to support a brain dead donor on organ support systems and to maintain the viability of and determine the suitability of

different organs and tissues. The Task Force is strongly in favour of reimbursing physicians for their care of the donor during this pre-donation phase of the transplantation process.

Pre-donation care describes the care required to maintain a donor on organ support systems from the time of brain death to donation, or the determination that donation is not possible.[5]

At present, physicians are paid a fee only for the removal of organs and tissues for transplantation. This fee is claimed by the physician through the recipient's health care insurance number. In the event the removed organs and tissue are not used, the physician may seek reimbursement for his effort by requesting consideration of his claim through the H.O.P.E. Program which has a modest budget for this rare event. Currently, this policy only applies to corneas and kidneys. No changes are suggested in the mechanisms presently used for reimbursement, only an extension in the scope of the mechanism.

Recommendation

It is recommended that physicians receive reimbursement for pre-donation care of brain-dead donors.

3.4 The Importance of Standards in Donation of Tissues and Organs

Concern has been voiced that the lack of standards for organ and tissue procurement procedures and for the preservation of organs and tissues may lead to confusion in applying donor selection criteria, to selection of unacceptable donors, to a poor surgical result, and perhaps to liability. Two dramatic reports of death

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[5]Donation may not be possible if the organs/tissue are damaged during maintenance or if a suitable recipient cannot be located. Pre-donation care does not imply a loosening of the standards and criteria for donation.

resulting from the implant of infected corneas, and one reported legal decision where two patients each lost sight in one eye, highlight the importance of stringent donor selection criteria. These cases are discussed in detail in Appendix N. The recent occurrence of an infectious blood-borne virus-associated, acquired immunodeficiency disease known as AIDS also emphasizes the strict care which must be taken in donor screening programs. Although the AIDS virus has not been detected in human corneas, the possibility that corneas may act as a carrier material for the virus is of extreme concern to physicians practicing in this area. This is discussed in depth in Appendix R.

The Task Force is of the opinion that standardized procedures for organ and tissue donation would ensure quicker recovery of donated organs and tissue with an increase in quality. Standard procedures would also offer some measure of certainty to medical staff in non-transplant hospitals who may perform such procedures infrequently.

In making the following recommendations, the Task Force wished to safeguard patient care in the province as well as provide medical personnel with protection from liability.

Recommendation

It is recommended that the hospital or institution where transplantation is performed should ensure that proper institutional policies regarding donor selection criteria be in place and that the donor's complete medical history is available for review at the time of donor selection.

Recommendation

It is recommended that, in non-transplant medical centres, strict criteria be in place regarding the identification of potential donors, the determination of brain death, and techniques for the surgical removal and subsequent perfusion and preservation of organs and tissue.

Recommendation

It is recommended that technicians should receive proper training for various tissue and organ procurement procedures at a recognised centre, and that the proper guidelines and procedures are in place regarding their duties and responsibilities.

CHAPTER 4: STANDARDS AND PROCEDURES RELATED TO THE DONATION, STORAGE AND UTILIZATION OF HUMAN ORGANS AND TISSUES

4.1 INTRODUCTION TO TISSUE BANKING

Nowhere is the difference between the two main types of transplantation surgery clearer than in the area of standards and procedures for donation, storage and utilization of human organs and tissue. For those organs requiring vascular anastomosis, or an immediate joining to the recipient's blood vessels, the so-called "solid organs" or "vital organs" such as kidneys, hearts and livers, surgeons must have almost immediate access to operating rooms, with an almost military organization of facilities and disciplined support staff. Such organs have a very limited potential for storage. By contrast those transplants not dependent on surgical anastomosis of their blood supply, transplants such as cornea, skin, bone, bone marrow and joints, have less immediate needs for early implantation, but pose storage problems which require considerable attention.

The ability to store tissue more extensively would greatly promote the transplantation process. For non-vital tissue, it allows retrieval of more tissue from a given donor than might be needed for a single procedure, so that many patients may potentially benefit. In the case of vital tissue and organs, short term "ex vivo" maintenance facilitates the cross-matching process by allowing selection from a greater pool of recipients.

Consequently, it must be recognised that the current needs, goals and aspirations of 'vital organ' transplant physicians and surgeons differ from the needs and aspirations of those who are concerned with transplantation of organs and tissues which do not require vascular anastomosis.

Tissue banks incur operational costs. Friedlaender[6] shows a 1976 operating cost of $165,690.00, excluding salaries for a standard, established tissue bank. The Canadian Red Cross study on the feasability of establishing a comprehensive tissue bank in Alberta including a research institute, suggested that in 1978 $388,000.00 would be required; with the inclusion of salaries the figure more than doubled to $863,000.00.

4.2 The History of Tissue Banking

Tissue banking or the storage of tissue for therapeutic purposes was first used on a routine basis with the blood banking units of the 1940s. Developments since that time have led to routine storage of blood[7], bone, skin, fascia dura, cartilage, tendon, nerves, heart valves, veins, arteries, bone marrow, sperm, and to a lesser extent cornea, for future therapeutic use. Currently, tissue banks range in size and complexity from comprehensive centres which may include research facilities and which provide tissue for therapeutic uses to a number of centres to small local operations providing one type of tissue for one physician, and under that physician's own responsibility. The latter is the only variety existing in Alberta, presently.

At one end of the spectrum of tissue banks is the U.S. Navy Tissue Bank, probably the largest, most comprehensive and most experienced tissue banking facility in the world. It provides not only the needs of the U.S. Navy but it also provides tissue to other medical centres and it includes a research facility.

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[6]*Personnel and Equipment Required for a "Complete" Tissue Bank*, in Tissue Banking for Transplantation, 1976 by Friedlaender, G.E., Grune and Stratton, Inc. at page 238.

[7]Blood is a tissue but it is not included in this discussion as the donation of blood is considered standard practice. Certainly the Red Cross concept of the blood bank as it exists in Canada is both efficient and standardized and as such it offers an admirable model for future tissue banks.

The smallest centres, at the other end of the spectrum, have household refrigerators or freezers containing small quantities of tissue that will be used for future transplantation needs of that centre. The processing of these tissues may be quite casual and it is not uncommon for hallways to be used as storage areas.

The Task Force has been concerned that such practices are not only inadequate from the point of view of proper preservation and storage but also potentially hazardous in that disease agents may be transferred with the tissue. Often local programs do not recognize the needs of the larger community and this may result in poor utilization of available tissue.

The Task Force examined an earlier proposal by the Canadian Red Cross for a comprehensive tissue bank. They conducted their own survey of the needs of Alberta physicians and met with the members of the Alberta medical and scientific community most closely associated with tissue storage to determine their views on the topic.

4.3 The Comprehensive Tissue Bank Proposal

In 1979, the Canadian Red Cross Society, which operates a Blood Transfusion Service Centre in Edmonton, submitted a proposal to Alberta Hospitals and Medical Care for the development of a comprehensive tissue bank as part of an approved expansion to the Blood Transfusion Centre. To support its proposal, the Red Cross tabled a feasibility study carried out by consultants, Education Health Environment, Ottawa Limited, which outlined the history of tissue banking, the then current scope of potential services, the functional relationship between the bank and the Blood Transfusion Service Centre. This study did not address the need for a comprehensive tissue bank in Alberta.

The report concluded that a comprehensive tissue bank be developed in conjunction with the Edmonton Blood Transfusion Service Centre. The preferred location was the University of Alberta campus. Justification for the co-ordination of effort was on the basis of resource and cost sharing, and exchange of expertise. The information on costs was quite dramatic, an independent bank was estimated to cost 29% more in terms of operating costs and 13% more in terms of capital costs than a shared facility. Locating the joint facility on campus would result in further cost savings. The study stated that Edmonton would be a proper location for a comprehensive tissue bank because of the outstanding biological and medical research laboratories located in Edmonton.

At the time of the Education Health Environment, Ottawa Limited proposal, it was difficult if not impossible to demonstrate the need for a comprehensive tissue bank. However, if the U.S. Navy Bank was any indication, the demand for tissue would always exceed the supply, and this point was made clear by officials of the Navy Bank who had travelled to Edmonton to provide the benefit of their experience and knowledge. Delays took the Red Cross project into leaner fiscal years and its future became uncertain.

4.4 Physician Utilization of Human Tissue for Medical Purposes in the Province of Alberta in 1983

A study undertaken by the Task Force during 1983 (Appendix J.1) indicated that many physicians who deal with transplant tissue would use tissue bank services, if they were available, and that some physicians were very interested in the establishment of such a facility. The Task Force report on physician use and acceptance of a tissue bank indicated that the geographic location of the tissue bank might be a limiting factor since physicians in southern Alberta would be

apprehensive about its utility if the bank was located in Edmonton. The supported advantages of a centralized tissue bank are the obvious ones: ease of co-ordination and quality control. The disadvantages are largely economic and geographic, it would be expensive to construct and operate, and if only one facility existed, its location would be controversial.

4.5 Submissions Made to the Task Force on the Need for a Tissue Bank in Alberta

In addition to its comprehensive study of this area, the Task Force invited the following speakers to present their views on tissue banking at a special meeting of the Task Force on Tissue Banking on July 18, 1984.

Dr. J.D.M. Alton
Edmonton

Dr. N. Boyd
Calgary

Dr. L. E. McGann
Dept. of Pathology
The University of Alberta
Edmonton

Dr. D. Modry
Edmonton

Dr. Jean-Michel Turc
Canadian Red Cross
Blood Transfusion Service
Edmonton

The testimony of the speakers is summarized in Appendix J.2.

4.6 The Current Situation in Alberta, and Perceived Need

The Task Force is of the opinion that there is need in Alberta for the storage of human tissue, other than blood and blood products. These are storable tissues such as bone and joints.[8] These tissues are usually taken from cadavers, but not necessarily in an operating room as is the case for the non-storable organs requiring almost immediate vascular anastomosis.

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[8]Osteoarticular bone implies joint with bone whereas "bone" itself can represent many entities, examples long bone, fragments of bone removed at surgery and bone products processed in the laboratory.

Solid organs are not presently stored anywhere in the world as the technology does not exist. Sperm and fertilized ova were not considered to be within the mandate of the Task Force although both can be "banked".

Skin, bone and joint each have the capacity to be stored in a frozen state for long periods at optimum low temperatures. The tissues remain viable at temperatures of -180°C; skin stored in this manner will "take" on a burn victim and is used as a long term form of burn dressing. Similarly, a joint may be successfully transplanted if certain other recipient criteria are satisfied. The storage and surgical techniques in these areas are well established and the immunological problems are small.

There is no central tissue bank in Alberta, although one was planned for the new Red Cross Building near the Mackenzie Health Sciences Centre in Edmonton (see Chapter 4.3). Some centres are storing bone but skin, long bones, joints (osteoarticular bone) and corneas are not being stored although there is an interest in the major cities in storing all four of these tissues. Interest in obtaining skin and joint/bone banking facilities has been expressed in Calgary and it is expected that the requirements will soon increase in Edmonton and possibly develop in one or more of the intermediate cities.

In Alberta, the Chief Medical Examiner has co-operated in supplying cadaver skin on an as-required basis (see Chapter 6.3 Chief Medical Examiner's Tissue Program) largely in Calgary, but this has never been stored. The lack of stored (frozen) skin has been of concern when demands by plastic surgeons for fresh skin cannot be met by either hospitals or the Chief Medical Examiner's program. Replacement of long bone or joint/bone (osteoarticular) by transplant has been slow to develop because of a critical shortage of these tissues. Each is suitable for storage if properly harvested and if the correct refrigeration is available.

There is no comprehensive tissue bank in existence in Canada. In fact, apart from Vancouver, where there is a small skin bank, and Quebec, where cornea storage is done on a routine basis, the Task Force did not learn of anything in the rest of Canada that was different from Alberta. The Task Force is not aware of the method by which corneas and skin requirements are met elsewhere; joint/bone storage is done occasionally in Calgary.

A similar situation exists in the United States although there are growing numbers of small "banks", each dealing with a distinctive tissue, such as the Shriners' Burn Institute in Boston and the Massachusetts Bone Bank also in Boston. Some of these tissue banks have a co-operative program, e.g. New England Tissue Bank. Additionally, there are up to 15 comprehensive units including Miami, San Francisco, Scranton, Pennsylvania, Denver, Detroit, St. Louis, West Virginia, each of whose activities are presumably large enough to supply material on a commercial basis. As well, the U.S. Navy Tissue Bank in Bethesda, Maryland has banked skin and numerous bone products for many years to supply institutions even beyond the military. It should be noted that the U.S. Navy Tissue Bank is primarily a research institution whose policy of supplying skin and bone to "outside" organizations is now being revised as other institutions develop "banks".

4.7 The Task Force Tissue Bank Proposal

The concern to have Alberta meet present and future needs in the area of corneas, bone and skin transplants must be weighed with aesthetic, political, economic, regional, professional and technical concerns in mind. As well, the size of the province, the ability to supply outside needs, and demand in general, must be clearly recognized before any major expense is incurred. The options suggested to the Task Force are:

- To develop one large comprehensive tissue bank in Calgary or Edmonton.
- To develop and support local hospital programs such as the Lions Eye Bank at Calgary's Rockyview Hospital.
- To support the Chief Medical Examiner's Tissue Program in Calgary and Edmonton.
- To promote the H.O.P.E. program in both Calgary and Edmonton to ensure proper co-ordination, co-operation, efficiency and economy in obtaining tissue and organs and in developing a central computer record of available stored tissue.

The Task Force is of the opinion that a large comprehensive tissue bank, including a facility suitable for processing the human body for organs and tissues, is not a reasonable proposition for the province of Alberta, at this time, for the following reasons:

1. storage is presently limited to a few types of tissue;
2. no specialized facility is required for procurement of currently storable tissues;
3. surgeons have expressed concern that moving away from the hospital operating suite to another site may result in a loss of the quality of donated tissue;
4. if against family wishes, would reduce the chances of consent; and
5. there is not at present, nor in the foreseeable future, a demand in Alberta for **large** amounts of frozen tissue.

Dr. G. Friedlaender, a recognized international authority on Tissue Banking and the first president of the American Council on Transplantation, has advised the Task Force that regional facilities are a viable concept even though a national tissue bank may not be viable at this time. Indeed, Dr. Turc, Special Advisor to the Task Force, has counselled "... it seems impractical and inadvisable for any

organization that is undertaking tissue banking to plunge in on a large scale right from the beginning".

Local hospital programs should also be discouraged because of the expense of duplicate facilities and the possibility of poor quality control. A co-ordinated approach will increase the chances of harvesting several tissues from one donor. A fragmented system may be inconsistent in its approach to relatives of potential donors and result in a loss of donations.

The lack of standards in bone and skin banking, indeed in tissue banking in general, is of serious concern to the Task Force and could be overcome by the development of a small tissue bank which could meet the needs of both cities.

A small tissue bank for skin and bone developed at the Medical Examiner's facility in Calgary has the following advantages:

1. It is central and would reduce the need for transportation of donors;
2. Donors at the Medical Examiner's facility consistently provide a reliable source of tissue since they are persons who died suddenly or accidently and were previously in good health;
3. The facility provides a good opportunity for quality control (standards) since it is in an established regional facility;
4. It is clear from several studies that shared facilities dramatically reduce costs;
5. The Medical Examiner's Program for Tissue Donation has proven to be a reliable and sensitive method of contacting next-of-kin, and it is compatible with the H.O.P.E. program which provides co-ordination of harvesting and distribution of the tissue, and record keeping.

Recommendation

It is recommended that the provincial government establish a tissue bank for skin, bone and possibly corneas. It is recommended that the unit be known as the H.O.P.E. Tissue Unit and that it be administered by the proposed umbrella organization.

Rationale

The lack of standards in tissue banking in Alberta is of serious concern to the Task Force and this difficulty could be overcome in part by the development of a small tissue bank to meet the needs of the province. In the near future two facilities will be required, one in Northern Alberta and one in Southern Alberta, to meet the needs of both urban centres. At present, the demand and need for such a facility appears to be higher in Calgary and the Task Force is of the opinion that the unit should first be developed in Calgary and then be expanded to Edmonton, depending on the demand for tissue.

The Task Force is of the opinion that a unit physically allied with the Chief Medical Examiner's Office would be the best choice for a tissue bank at this time. The Task Force also recognises that the proper functioning of an Alberta tissue bank may require reorganization and further co-operation among present programs.

CHAPTER 5: THE LAW AS RELATED TO THE DONATION, STORAGE AND DISTRIBUTION OF HUMAN ORGANS AND TISSUES

5.1 Historical Background

The roots of present day legislation regarding organ transplantation are to be found in the old English common law concerning cadavers. Under the common law human remains were not considered property.

The common law was sketchy and its only requirement was that the deceased's executor or legal equivalent had a legal obligation to bury the body of the deceased. The person[9] charged with the legal obligation of burying the deceased, was not bound to carry out any previously expressed wishes of the deceased regarding the disposal of his remains. The duty of the personal representative to bury the corpse became converted into a right of possession or qualified property in the corpse. Thus, if a third person interfered with the right by taking the body or part of it, the personal representative of the next-of-kin had an action.

The classic case in this area is Williams v. Williams (1882), 20 Ch. D. 659, where at 665 of the report, the court held:

> "... after the death of a man, his executors have a right to custody and possession of his body (although they have no property in it) until it is properly buried ... .
>
> It follows that a man cannot by will dispose of his dead body. If there be no property in a dead body it is impossible that by will or any other instrument his body can be disposed of ... ."

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[9]This could be the executor, surviving spouse or next-of-kin

Cadavers were in great demand in England at the beginning of the nineteenth century. Body snatching was common. The scandals of body snatching and murder led to the passing of England's Anatomy Act in 1832 to provide a supply of cadavers for the study of anatomy. This legislation provided that unclaimed bodies of persons who died in public institutions could be given to medical schools for anatomical examination and further provided that such bodies must be properly buried after examination. The Anatomy Acts did not permit the removal and retention of parts of a cadaver. After examination, the human remains were to be buried.[10]

The successful development of the corneal grafting operation as a method of treating blindness focused attention on the legal impossibility of post mortem donations of cornea. To remedy this deficiency, Britain passed the Corneal Grafting Act in 1952 to permit persons to request post mortem cornea donations. The common law influence remained however since the Act left the final decision on donation to the surviving spouse or nearest relative.

New Brunswick was the first Canadian common law province to enact corneal transplant legislation. In 1959 the Conference of Commissioners on Uniformity of Legislation adopted a Uniform Cornea Transplant Act which was substantially similar to the English and New Brunswick legislation and which was adopted by all of the common law provinces and the two territories.[11]

England replaced the Corneal Transplant Act with the Human Tissue Act in 1961, which extended donation from corneas to all human tissue for therapeutic, educational or scientific purposes. In 1963 Ontario replaced its Corneal Transplant

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[10] Neither the Anatomy Act nor its Alberta equivalent, the Universities Act, permitted the removal and retention of parts of a deceased person for medical purposes whether for therapeutic, educational or research purposes.

[11] Uniform Law Conference of Canada, (1958 Proc. 28 and 1959 Proc. 21 and 76).

Act with the Human Tissue Act.

In 1963 the Uniform Law Conference agreed to look at a Human Tissue Act, since Britain had enacted such a statute in 1961 (1963 Proc. 23). The task was assigned to the Alberta Commissioners. In their report (1964 Proc. 63) they raised the policy issue: should the wishes of the deceased that his body be available after death for therapy, etc. be binding instead of being subject to the decision of someone else? The conference agreed. In 1965 the Conference of Commisssioners on the Uniformity of Legislation in Canada formally adopted the Uniform Human Tissue Act and recommended its enactment. Hence the Uniform Human Tissue Act (1965 Proc. 25, 63, 104).

In 1968 Alberta enacted the Uniform Act.

In 1970 the Ontario Commissioners proposed a new Human Tissue Act which the conference adopted forthwith (1970 Proc. 36 and 138). The main purpose was to deal with *inter vivos* gifts which are covered in Part I. Part II is almost the same as the 1965 Uniform Act while Part III contains some general provisions.

After the 1970 meeting of the Uniform Law Conference the Ontario Legislature examined the new Uniform Act. In passing it the Legislature made some changes including a change of title to the Human Tissue Gift Act. In light of the Ontario changes, the Ontario Commissioners returned to the Uniformity Conference in 1971 and requested the Conference to adopt the Ontario Act. This the Conference did (1971 Proc. 76, 144).

The salient features of Alberta's Human Tissue Gift Act are as follows:

- permits post mortem donation of body parts by individual or family;
- permits **inter vivos** donation of tissue by person of the age of majority;

- outlines a priority list of persons who may give consent to organ donation in the event of the death of another person.
- permits a Medical Examiner to give consent to donation when previous family consent was obtained, but when the Fatality Inquiries Act applies;
- states that death shall be determined in accordance with accepted medical practice;
- prohibits physicians who are associated with the proposed recipient from taking part in the determination of death of the donor, and also prohibits the converse, that is, physicians who determine death may not take part in the transplant procedures;
- excuses physicians removing corneas from requirements regarding determination of death;[12]
- states that tissue which are not capable of being used are to be dealt with and disposed of as if no consent had been given.
- there is an exemption for civil liability for damages against a person for acts done in good faith under the Act (good faith exemption from civil liability);
- there is an absolute prohibition on sale in any form of tissue (except blood);
- there is a provision for confidentiality of information regarding a donor or recipient except when legally required or when a person discloses information pertaining only to themselves.
- there are the usual safety mechanisms which state that the Act does not make illegal anything that was legal before the Act was passed with regard to dealings with a body or part of it; provides that it does not affect the Fatality Inquiries Act except as mentioned; and makes it an offence to knowingly contravene the Act subject to a fine of $1000 or 6 months

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[12]Note: in practice corneas are removed only when a patient has been declared dead and is no longer on organ support systems. Corneas may be removed up to six hours after the time of death.

imprisonment or both.

5.2 Definition of Death

Until very recently law and medicine accepted the same definition of death which was defined as "the total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc." Medical technology can now maintain such functions in a person by mechanical means long after the brain has ceased to function. This has led to a re-evalution of the traditional definition of death in medical circles and the acceptance of brain death as the death of the individual.

Some jurisdictions have given legal recognition to the concept of brain death.

Manitoba legislated the following definition in 1975:[13]

> "For all purposes within the legislative competence of the Legislature of Manitoba the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs."

It should also be noted that Manitoba is the only province where brain death has become a legal issue. See the case of Regina v. Kitching and Adams [1976] 6 W.W.R. 697 (Manitoba Court of Appeal) discussed at length in Appendix J.1.

The difficulty with a legal definition of death is that death is a biological process and the law requires an event or point in time beyond which the person is regarded as dead. It is possible to place this point in time anywhere along a

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[13]Vital Statistics Act, S.M. 1975, c. 5, s. 7.

continum of dying from permanent loss of ability to interact with one's surroundings, to death of the whole brain, to total cellular death.

While brain death is recognised medically as the death of a person practical difficulties still occur. The Task Force have reviewed some of the practical problems, see Appendices J.1 and J.2.

In order for donation of organs and tissues to occur, it may be necessary to transfer a person identified as a potential donor, maintained on support systems, or a body identified as a potential donor maintained on organ support systems, from hospital to hospital within Alberta, or from a hospital outside Alberta to one within Alberta, or from within Alberta to outside Alberta. The situation is covered by existing legislation unless the person has been diagnosed as brain dead before transport. If the person is brain dead, it is a dead body, not a person, which is being transported, albeit under circumstances where organs are being perfused by a maintained blood circulation and artificial ventilation.

Administrative difficulties may occur if the potential donor on support systems has been declared dead before the decision to transfer to the transplant hospital. The situation is difficult because hospitals do not admit dead bodies and because transport is restricted by public health laws and regulations on the removal and transportation of dead bodies. In Alberta, see for example Section 25(1) of the Operation of Approved Hospitals Regulations, A.R. 146/71 as amended to A.R. 226/82; Sections 15 and 16(1) of the Fatality Inquiries Act, R.S.A. 1980, c F-6; Sections 14(3)(a), 18(3) and 18(5) of the Vital Statistics Act, R.S.A. 1980, c V-4, and regulations regarding the transport of bodies affected by specific communicable disease, such as the Provincial Board of Health Regulations Respecting Preparation and Transportation of Dead Bodies, Funerals, Interment and Disinterment, A.R. 227/73, as amended by A.R. 336/75.

Technically, the above legislation might apply to a brain dead donor on organ support if death had been determined before transport, even if the death certificate had not actually been signed. In practice, to date, the potential donor is treated as a patient and transported as such. In one centre in Alberta, by convention, the time of death is stated as the time when mechanized support is discontinued. While this may seem reasonable at first glance, it leads to a double standard as far as death and organ transplants are concerned, as that same donor would previously have been determined to have been brain dead, elsewhere. Such unacceptable ambiguity would not be necessary if new regulations were drafted for ambulance transfer, hospital admission and other administrative aspects of handling brain dead donors.

Legal difficulties may occur after admission if the donor is admitted to the hospital as the patient of a physician involved in the subsequent transplant. These difficulties would occur because the admitting physician is considered responsible for the patient/donor. Thus if the patient/donor is determined to be brain dead after admission, the admitting physician will be responsible for that determination since it was done at his request and under his authority. The physician is then precluded from participating in transplantation by virtue of sections 7(2) and 7(3) of the Human Tissue Gift Act.

The Task Force recognises the difficulties in grappling with such situations and suggests that some of the practical difficulties which occur in Alberta may be solved in the following manner.

Recommendation

It is recommended that uniform protocols be established to permit the admission, transfer and transport of brain dead donors, on organ support systems,

to transplant centres for the purposes of organ donation and retrieval.

Recommendation

It is recommended that the provincial government develop a policy for a) payment of transportation expenses for donors or donor organs, incurred in relation to human organ and tissue transplantation, b) related hospital costs, and c) return of the donor body for burial.

5.3 Why the Universal Donor Card is Not a Will

It has been suggested that the form of donor card on a driver's licence may be a will because it provides for two witnesses and that it would then be automatically revoked by the donor's will which usually begins "I hereby revoke all former wills and testaments..."

The provision for witnesses on the donor card does not turn donation into a will for the following reasons. First, the Human Tissue Gift Act in Alberta (section 4(1)) only requires writing and signature to make a donation of tissue. Second, even assuming that the Human Tissue Gift Act, like the American Uniform Anatomical Gift Act, required two witnesses, this requirement does not make the gift document into a will, since the Wills Act, R.S.A. 1980 c. W-11, only permits the disposition of real or personal property by wills and there is no legally recognised property in a dead body.[14]

Even if Alberta's Human Tissue Gift Act did require two witnesses to a donation, **that fact alone would not convert it into a will.** Since the Alberta Human Tissue Gift Act does not require witnesses if the gift is written, the suggestion that it is a will has no justification.

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[14]See the case of Williams v. Williams discussed in Chapter 5.1.

The point is of importance not only in Alberta, but elsewhere, in Canada because all provinces and both territories in Canada provide for post mortem gifts of tissue. All the laws require the gift of tissue to be in writing and none requires a witness, where the gift is written. If a will made after the gift of tissue altered the donor card gift the result would be regrettable. However, the standard revocation clause in a will does not normally rewrite the gift of tissue for the reasons discussed above.

CHAPTER 6: ORGAN AND TISSUE DONATION PROGRAMS IN ALBERTA

6.1 The Human Organ Procurement and Exchange Program

At the present time in Alberta most human organ and tissue donation is co-ordinated through the Human Organ Procurement and Exchange (H.O.P.E.) Program. The H.O.P.E. program began in December of 1978 when the Alberta branch of the Kidney Foundation of Canada received a grant of $50,000 from the Government of Alberta. The program co-ordinates the exchange of patient data between different transplant centres and handles data concerned with kidney, cornea and other organ and tissue donation, and transport and promotes awareness of transplantation throughout the Province of Alberta by various educational programs. The programs became operational October 15, 1979 when co-ordinators were appointed for the City of Calgary and the City of Edmonton. These co-ordinators work out of the Foothills Provincial General Hospital and the University of Alberta Hospitals. Although the program has only been operational for a few years, there is good evidence that it has increased the number of donations and transplants in Alberta (see Appendix F).

In May of 1983 the Task Force examined the work of the H.O.P.E. Program in light of present advances and demands of transplantation medicine. The Task Force was of the opinion that the H.O.P.E. Program be continued in essentially its present form throughout the fiscal years 1984 to 1985 and 1985 to 1986, focusing as it does on donation and exchange of kidneys and corneas, but that the program budget should be specifically increased in the areas of funding for publicity and advertising addressed to the general public, funding for new videotape programs addressed to health professionals, and funding for increased support staff in order that it meet the needs in the province.

It is also recommended that the expanded H.O.P.E. program play a crucial role in two critically important areas cited below: a) the crisis in the operating room of a transplant hospital after multi-organ procurement; and b) in facilitation of the Medical Examiner's tissue procurement programs.

6.2 Proposed Expansion of Personnel Support Programs for Transplantation

Access to operating theatres is a serious practical problem and has been identified by the Task Force as a real barrier to transplantation in Alberta. There is concern regarding the present delay in operating room space available for the donation of kidneys and corneas and their transplantation. The most common organ transplants in Alberta are cornea and kidney transplants, which are carried out on an emergent or semi-emergent basis. This means that patients receiving these transplants must wait for access to the operating theatre with all other emergencies in the hospital and elective cases booked for surgery. Absolute priority cannot be given to the transplant surgeon for these surgical cases. In the recent past, patients have travelled for several hours from some remote area in Alberta with utmost urgency, on being called for a kidney transplant, only to then have wait for twelve to eighteen hours before being brought into the operating room. It is during this period of time that the function of the ex vivo organ may deteriorate.

With the anticipated development of cardiac, liver, and pancreas transplant teams, the kidney and cornea transplant surgeons foresee even greater difficulty in obtaining adequate operating room space, nursing staff and facilities. This could lead to a situation that, when a donor is available, two kidney transplants, two corneal transplants, one heart transplant and one liver transplant would have to be performed almost simultaneously. This would involve a significant amount of operating room time and staff, perhaps for as long as eighteen to twenty hours.

The first heart transplant in western Canada was performed by Dr. D. L. Modry at University of Alberta Hospital, Edmonton, Alberta on July 28, 1985. This was the first of three heart transplants proposed at the University Hospital. The heart donor died from head injuries suffered in an accident, but had previously signed a donor card. This evidence of intention to donate was also unanimously ratified by the family. Both kidneys and both corneas were also donated and were transplanted into four other people following the historic heart surgery.[15]

The delays that presently occur jeopardize the donation of organs by the donor and the functioning of the transplant in the recipient. Dedicated transplant operating room nurses would expedite organ implantations with improved early graft function.

Recommendation

It is recommended that additional funding be provided to the H.O.P.E. program to establish positions for six nurses who would be trained to assist in the operating room in the various transplant procedures, including donation and recovery of organs and tissue.

Rationale

Because of present difficulties experienced by transplant surgeons and because of the very real possibility that these difficulties will increase with increased transplantation procedures, a dedicated nursing/surgical support team is required to assist in the operating room. The team would form an integral part of the Council for Transplantation/H.O.P.E. program and would also assist the H.O.P.E. co-ordinators with donation of organs and tissue, counselling regarding organ

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[15] The cost of the three proposed heart transplants is estimated at $50,000 each with another $114,000 required in related costs, is being absorbed by the hospital budget.

donation and the like.

The dedicated operating room transplant team would eliminate delays in obtaining a functional operating room unit and would allow surgical procedures to be accomplished in an expeditious manner. This is the only way to ensure that people and hospital facilities will be brought together on short notice to maximize the survival potential of a vital graft and honour the generosity of the donor.

6.3 The Chief Medical Examiner's Tissue Program

In November, 1983 the Chief Medical Examiner's Office contacted the Task Force and indicated that they were willing to obtain consent for removal of certain tissue from the next-of-kin of recently deceased persons being examined at the facility.

It was the concern of the Task Force that such a request, which is made almost immediately, as the cornea must be taken within six hours of death, might be considered callous and untimely. The Chief Medical Examiner learned of an existing program in Dallas, Texas, that had operated successfully for some years without offending next-of-kin or the public, and visited Dallas in February, 1984 to study the details of their program. He also visited briefly with the Chief Coroner in Ontario whose office had, over the years, made requests of next-of-kin for consent to take cornea on an "as required" basis. After receiving approval for the concept from the appropriate ministers of Government, a limited approach began through the Chief Medical Examiner's Office in Edmonton in August, 1984.

The Program

A comprehensive training protocol for investigative staff was developed before the pilot program was initiated by the Chief Medical Examiner's Office in

Edmonton. As well, there was substantial media coverage just before the program began on August 15, 1985.

Bodies arriving at the Chief Medical Examiner's offices for post-mortem examination are assessed for suitability as donors. The criteria for determination of a person as a potential donor are: age, between 4 and 60 years; death within the preceding six hours; and absence of medical contraindications for cornea donation. If the deceased is determined to be a suitable donor, a member of the investigative staff contacts the deceased's family. Donation is discussed in a tactful and positive manner, and the family is permitted to make an informed consent. When the request is made in person, a consent form is signed; if over the telephone, the conversation is recorded. The donating family are advised in a general way that the tissue was used and was gratefully received.

By the autumn of 1984, the success of the Edmonton program became apparent and it was decided to expand the program to Calgary in mid-February, 1985. Again, training for Medical Examiner's Investigators was carried out, and the media, local ophthalmic surgeons and funeral directors were briefed.

The program was well received by interested groups and the public. The level of interest was high clearly because of the newsworthiness of human drama, in this instance tragedy, potentially mitigated or potentially deepened by the hand of government. Neither adverse publicity nor adverse individual comment, including redress by next-of-kin, has been received in either city to date.

The role of the H.O.P.E. program co-ordinators has been substantial, allowing for the Medical Examiner's Investigators and mortuary staff to deal exclusively with next-of-kin and the donor. In Edmonton and Calgary, the H.O.P.E. co-ordinators, Pauline McCormick and Janice Mann, have made all the arrangements

for the surgeons to be notified and to attend at the Medical Examiner's facility at a scheduled time with appropriate equipment both for taking the eyes and transporting them to the recipient. Recently, the Lions' Eye Bank technologist in Calgary has become involved in the enucleation, assisting the surgeon and relieving the Calgary H.O.P.E. co-ordinator of this task.

Conclusions

Statistical material (see Appendix O) indicates that the program is very successful. In part this is due to the enthusiastic support for the program by the medical investigators, five in each principal city, all of whom are nurses. It is worthy of comment that the key factor for success of the Alberta Medical Examiner's system is a proper concern for the next-of-kin. The Chief Medical Examiner has expressed the opinion that this is the single most important item accounting for both the absence of "bad press" and the high success rate in obtaining consent to organ donation.

It is important to point out that one of the reasons given by the medical profession for their reticence[16] in approaching next-of-kin for consent to organ donation is their belief that donation would be refused. This belief is unfounded since this program, although limited, already has a considerable success rate.

The Chief Medical Examiner has discussed similar arrangements with plastic surgeons and one orthopaedic surgeon with regard to obtaining donation of skin, bone and joint tissue for their use in the future. These tissues can be taken without the severe time constraints encountered with corneas. Additionally, skin and bone/joint tissue lend themselves to long term storage, an advantage not presently available for corneas. There seems to be no reason why these two tissues cannot be

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[16]This reticence is widely held as a major reason for the shortage of transplant tissue and organs.

added to the program now on an "as-needed" basis, in the hope that proper storage arrangements will be made in the future.

Recommendation

It is recommended that the Chief Medical Examiner's Program for donation of storable tissue become a permanent provincial program and that it become an integral part of the proposed Council.

Rationale

The Medical Examiner's pilot program of obtaining consent from relatives for donation of corneas of recently deceased persons being examined at the Medical Examiner's facility has met with considerable success both in Edmonton and Calgary.

In Edmonton, in a 9-month period from August 1984 to April 1985, a total of 27 pairs of eyes or 54 eyes were donated. This represents 37.5% of all eyes donated in Edmonton during that period of time. If the program can keep its present level of donations, the period of time a patient must wait for a corneal transplant will be markedly reduced.

CHAPTER 7: DISPOSAL OF HUMAN TISSUE

7.1 Disposal of Donated Transplant Materials

Kidney Transplants

When transplantation of a kidney cannot be accomplished because of technical surgical problems or an immunological mis-match, the kidney is submitted to the pathology department for histological studies. Such studies assist physicians in determining the effects of ischemia[17] and preservation techniques and rule out any unsuspected disease processes.

Cornea Transplants

It is the policy of the Corneal Service at the University of Alberta Hospitals to accept all eyes which are donated. The donor's family is always advised that the eyes will be used for corneal transplantation if possible but if they are not suitable they will be used for research or teaching. Following removal of the cornea the scleral shell is preserved as required. The remainder of the eye is disposed of through the standard procedure carried out by the University Hospital for tissue removed in the operating room.

Eyes which are not suitable for corneal transplantation are utilized in the microsurgical teaching laboratory, an essential part of the resident training program at the University of Alberta Hospitals.

7.2 Disposal of Retained Autopsy Materials

Occasionally, samples of human tissue must be retained after autopsy for proper examination. This might preclude the return of some specimens to the body

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[17]poor blood flow

at the completion of the autopsy. The body is then released for burial without the tissue which is later disposed of. The Task Force was approached by members of the medical profession who were concerned that the retention of human tissue at autopsy for subsequent pathological examination and the detailed disposal of such tissue might be a source of liability. The Task Force have investigated this matter (see Appendix M) and have come to the following conclusion.

Recommendation

Consent to Autopsy

It is recommended that, on the advice of the Minister, each hospital's consent to autopsy form be broadened to include authorization for retention of tissue and organs as part of the autopsy process.

Recommendation

Disposal of Tissue

It is recommended that, on the advice of the Minister, hospital by-laws and laboratory procedures be reviewed appropriately to ensure proper, dignified disposal of human tissue.

Rationale

Although s. 44(1)(f) of the Hospitals Act, R.S.A. 1980, c. H-11 and s. 68(d) of the Mental Health Act, R.S.A. 1980, c. M-13 permit the Lieutenant-Governor to make regulations regarding "the disposal of human tissue, whether removed during an operation, autopsy or otherwise", there is no legislation or regulation providing for the manner of human tissue disposal. Since legal difficulties which have occurred in the United States regarding the retention and incineration of human tissue after operation or autopsy have been resolved without

legislation, it is the opinion of the Task Force that legislation or regulation on the manner of disposal of tissue is not required at this time. However, the Task Force is of the opinion that hospital policies and hospital "Consent to Autopsy" forms should be reviewed to determine if they adequately deal with these matters.

CHAPTER 8: THE ESTABLISHMENT OF A COUNCIL FOR TRANSPLANTATION IN ALBERTA

8.1 Outline of the Functions of the Council

The transplantation of organs and tissue in the Province of Alberta has developed on a gradual basis during the last two decades, as progress has been made in medical science and the techniques of transplantation. At present, the main activity takes place in principal hospitals in the Province's two major population centres, Edmonton and Calgary. The very nature of transplantation, however, is such that it cannot be conducted effectively on a hospital-by-hospital basis; there must be liaison and co-operation between hospitals and medical institutions in the urban centres in the Province and throughout the region. Organs both suitable and compatible for transplantation in a given hospital program cannot, under normal circumstances, be provided by the donors in that hospital alone. Likewise, the storage of organs for transplantation, particularly as more advanced methods are developed, is not either economical or efficient on a hospital-by-hospital basis. The utilization of organs will be more efficient if it is based on a Province-wide information network.

The logistical problems of the shortage of human organs for transplantation are <u>not</u> comparable to a shortage of resources or facilities which may occur in another branch of medical therapy, such as programs for management of trauma, or units for multiple sclerosis or neonatal care. It is not possible to consider the donation of human tissue and organs as equivalent to equipment or facilities because of the profoundly human component of these donations and the way in which they raise issues of deep emotional and spiritual concern with the public.

The mandate of the Task Force[18] did not include a full examination of the ethical issues of transplantation. However, the Task Force soon realised that it is not possible to deal with the issues of procurement, storage and utilization of human tissues and organs without also being involved with social, cultural, religious, and ethical issues in the whole field of transplanation.

In transplantation medicine, technical, administrative, professional and governmental concerns involve more than logistical or fiscal solutions, important as these may be.

It is for these reasons that the Task Force, charged with the task of looking into the whole question of organ procurement, has recommended a Council for Transplantation rather than an Advisory Committee on Human Organs and Tissue Procurement. In so doing, the Task Force recognises that the medical and scientific aspects of organ procurement are inextricably interwoven with wider legal and ethical aspects of transplantion medicine, as a whole.

The recommendation that follows proposes, in broad outline, a Council for Transplantation, the nature of the Council, its terms of reference, its principal functions, and an estimate of its requirements.

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[18]See Appendix B.

Recommendation

It is recommended that the Province establish a "Council for Transplantation" which would be responsible for:

a. promoting transplantation through extensive and continuous public and professional education, including ongoing examination of ethical and legal issues;

b. facilitating procurement, utilization and exchange of organs and tissue;

c. providing for storage of organs and tissue;

d. establishing and recommending on standards pertaining to all aspects of transplantation within its jurisdiction;

e. providing information on availability of organs and tissue on a provincial, national, and international basis.

Rationale

The conclusions drawn by the Task Force study on the *donation, storage* and *utilization* of organs and tissue is that extensive Province-wide co-ordination is required. This co-ordination would range from actual donation and storage, to liaison between medical institutions with respect to donation, storage and utilization of organs and tissue throughout the Province. Notwithstanding other recommendations contained in this Report, designed to increase the supply and improve the utilization of organs and tissue, the establishment of a Province-wide organization concerned with transplantation will improve the provincial transplantation situation, simply by ensuring better use of organs and tissue currently available.

In addition, ethical issues in transplantation must be addressed in a systematic and thorough fashion in order to provide the government with sensitive, responsive and expert opinions on these important issues.

The proposed Council would have essentially two component parts:

1. The Council as such, which would be advisory to both government and the medical profession on matters pertaining to transplantation including the procurement, storage, and utilization of organs and tissue; and
2. The Council's administrative and executive arm, with a small permanent secretariat which would offer specific services in relation to the procurement, storage, and utilization of organs and tissue.

8.2 Terms of Reference of the Council

The Council

The members of the proposed Council would be appointed by the Minister of Hospitals and Medical Care in consultation with appropriate professional bodies and voluntary organizations. Membership on the Council would normally be for a period of three years, renewable once.

Membership

1. Chair
2-4. Three representatives of the medical profession,
5. A hospital administrator,
6. A representative for non-government organizations (Red Cross, etc.)
7-9. Three members of the public including a representative of the business community,(some or all of these could be recipients of transplants)

10. A representative of the legal profession,
11. An ethicist, and
12. Executive Director of Council, this executive officer would be non-voting and would hold the post *ex officio*.

The Council shall have a recording secretary.

Terms of Reference

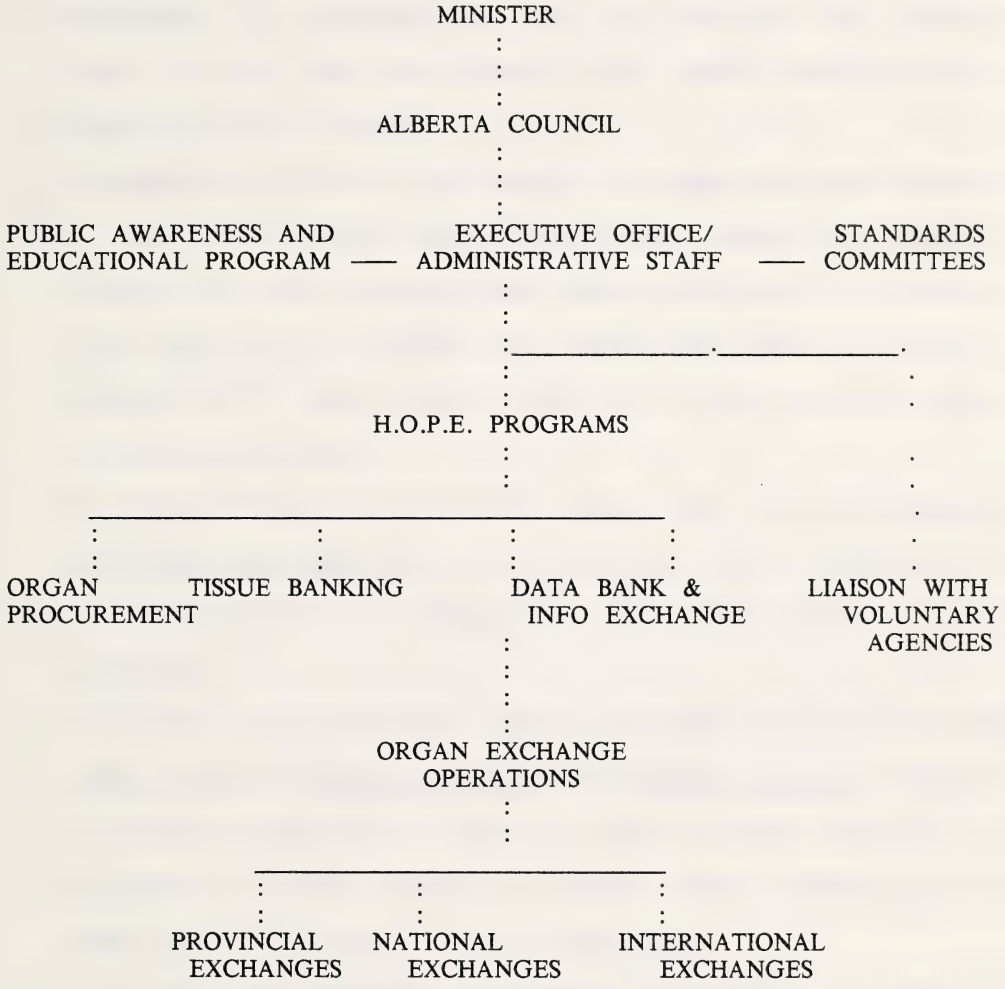
1. The Council is advisory to the Minister in all matters pertaining to transplantation, including the issues of procurement, storage, and utilization of human organs and tissue as well as ethical and legal issues;
2. The Council also serves as the advisory committee for the Executive Director of the Council, advising and making recommendations with respect to the Council's specific mandate;
3. The Council shall meet at least four times per annum;
4. There shall be an executive committee of the Council to advise the Executive Director on a month-by-month basis.

8.2 Administrative Structure of the Council

The following paragraphs list the administrative functions of the Council. Other responsibilities could be added to this from time to time. Table 8.1 (overleaf) provides an overview of the Council's structure and operation. Details of the specific operations such as tissue banking, the H.O.P.E. program, and the Chief Medical Examiner's Tissue Program are covered in other sections of this Report.

- The H.O.P.E. programs in various centres would be co-ordinated and funded through the Council.

TABLE 8.1: PROPOSED COUNCIL FOR TRANSPLANTATION



- Tissue banking, and organ storage; co-ordination and exchange of information between currently existing banks would be maintained. In the event of the establishment of a provincial tissue bank, the establishment and operation would be of the tissue bank assumed by the Council's administrative arm through the H.O.P.E. program.
- A data bank on needs for, and availability of, organs and tissue, employing an up-to-date computerized communications and data banking system, would be established. The central computing system would be established in the Council's office; access would be established on a provincial basis through the H.O.P.E. programs, and the system should be interlocked with other provincial systems and international systems.
- The Council through its Director would maintain liaison with various voluntary and service organizations such as the Red Cross, Kidney Foundation, and Lions and provide a co-ordinating role between the activities of such organizations.
- The Council, through its Director, would be responsible for various kinds of public awareness, professional awareness and educational programs, throughout the Province, designed to (a) increase the supply of organs and tissue, and (b) educate the medical profession, the medically related professions and the general public on all aspects of human transplantation.
- The Council would recommend to the Minister on standards on the advice of its standards committees.

8.3 Estimated Requirements

An important preliminary consideration in any discussion of costs of transplantation is the larger financial picture of which transplantation constitutes only

one part. Thus, as has been indicated in Appendix G.2, one single successful kidney transplant, when compared with the costs of a patient on dialysis over many years, results in a saving of many thousands of dollars. The annual cost of maintenance on dialysis ($30,000 per patient) is 3-5 times that of management of a successful transplant ($8,000 per patient). While the initial costs of establishing a Council on Transplantation and its associated programs, would be considerable it could in the long run be more than offset by the overall savings to the provincial health care budget effected by means of a promoted and improved transplantation program.

1. Capital Cost Estimates

It is difficult to provide an estimate of initial capital costs, because of the options available to the Government. (i) Available space could be utilized, without capital construction, so that the costs would be essentially those of operating and maintaining the space. (ii) A second option would be to combine the physical headquarters of the Council with a building associated with its operations, that is, with the proposed provincial tissue bank. The capital costs, supplementary to those involved in a tissue bank construction, would be relatively modest.

2. Location

One aspect of the capital costs of establishing a centre for the Council is its physical location. Options include one of the major urban centres (Calgary or Edmonton) or a central location between the two (e.g. Red Deer). In either (or any) of these centres, the Council should be in physical facilities which distinguish it from a major hospital (lest the Council's programs be viewed as merely an adjunct to the hospital's programs); however, if provincial government space were available in one of the possible locations, it could be appropriately utilized for the Council's physical

headquarters.

3. Equipment Costs

Basic requirements would be furnishings and supplies, together with a central computing facility.

4. Space requirements

Space requirements could be estimated in the following manner, depending on the physical location of the space. Metric conversion will be required.

Council Offices

Offices (5.0)	2,000 sq. ft.
Storage	400 sq. ft.
Computing facility	400 sq. ft.
Meeting room	500 sq. ft.
	3,300 sq. ft.

Tissue Bank

Laboratories and Surgical Suite	2,000 sq. ft.
Storage (including refrigerated space)	400 sq. ft.
Computer terminal	100 sq. ft.
Meeting room	300 sq. ft.
Offices	800 sq. ft.
	3,600 sq. ft.

Operating Costs

The following estimates are based on an initial operating basis and include the Council, the tissue bank proposal, and expanded H.O.P.E. proposals. Some costs (*) have been averaged over two years to offset the large establishment costs (e.g., meetings of Council and advertising).

The estimates include:

- general operating costs such as utilities, telephones, office supplies and laboratory supplies,
- staff salaries and benefits,
- computer costs and maintenance,
- costs associated with meetings of the Council and its executive committee including travel, extra-provincial travel, honoraria, and meeting costs,
- advertising expenses,
- special projects and educational aids (e.g., audio-visual aids).

Summary: Budget

a) Space requirements

Council Offices		3,300 sq. ft.
Tissue Bank		3,600 sq. ft.
Total Space Requirements (could be expanded to include additional 500 sq. ft. for local program)		6,900 sq. ft.
Council Offices (leased at $20/sq. ft.)	$66,000	
Tissue Bank (leased at $20/sq. ft.)	$72,000	
Lease total		$138,000
b) Capital Equipment costs		
i. Council	$30,000	
ii. Tissue bank	$315,000	
TOTAL Capital Costs		$345,000
c) Annual operating Costs of Council	$366,000*	
Annual operating Tissue Bank	$196,000*	
Annual operating H.O.P.E. Expansion	$570,000	
Total Annual Operating Costs		$1,207,000*
Cost Overall for First Year of Operation		$1,552,000

* Lease costs from (a) above are repeated in these figures.

TABLE 8.2: ESTIMATED OPERATING EXPENSES

COUNCIL FOR TRANSPLANTATION

Capital Costs		
Furnishings	$5,000	
Computer, dictation equipment and typewriters	$25,000	$30,000
Operating Costs		
Space, if leased		$66,000
Salaries and benefits		
Director (1.0)	$50,000	
Secretary (1.0)	$25,000	
Administrative Assistant/H.O.P.E. Liaison	$30,000	
Computer operator/Research Assistant	$20,000	
Salaries	$115,000	
Benefits (20%)	$25,000	$150,000
General operating costs		
Utilities and telephones	$10,000	
Computer operations	$10,000	
Office supplies	$ 5,000	$25,000
Special Projects		
*Public and professional awareness and education (e.g., advertising)	$75,000	
*AV Production	$25,000	$100,000
*Honoraria to council		$10,000
Travel - employees and council*		$15,000
TOTAL Annual Operating Costs		$366,000

* Two year average

Proposed Function of the Council

a. promoting transplantation through extensive and continuous public and professional education, including ongoing examination of ethical and legal issues;

b. facilitating procurement, utilization and exchange of organs and tissue;

c. providing for storage of organs and tissue;

d. establishing and recommending on standards pertaining to all aspects of transplantation within its jurisdiction;

e. providing information on availability of organs and tissue on a provincial, national, and international basis.

TABLE 8.3: ESTIMATED OPERATING EXPENSES
TISSUE BANK

Space, if leased		$72,000
Personnel/salaries		
Technicians (2.0)	$70,000	
Benefits	$14,000	$84,000
General operating		
Utilities and telephones	$5,000	
Computer costs	$5,000	
Laboratory supplies	$20,000	$30,000
Travel and courier services		$10,000
TOTAL Annual operating cost		$196,000

Proposed Function

a. to act as a central tissue bank to receive, process and store donated tissue

b. to provide tissue to physicians in the province

c. liaison with other tissue banks including blood banks to ensure more efficient use of tissue

TABLE 8.4: CAPITAL EQUIPMENT COSTS

Tissue Bank		
Skin processing and storage	$60,000	
Bone processing and storage	$95,000	
Corneal processing	$60,000	
Back-up refrigeration and alarms	$20,000	
Surgical suite	$65,000	
Computer and software	$15,000	$315,000
Council		
Computer, dictation and typewriters	$25,000	
Furnishings	$5,000	$30,000
TOTAL		$345,000

TABLE 8.5: ESTIMATED OPERATING EXPENSES

EXPANDED H.O.P.E. PROGRAM

Space (in each of two hospitals, Calgary and Edmonton)		$20,000
Personnel salaries		
Nurse/Surgical Assistant(6.0)	$210,000	
Secretary (0.5 x 2)	25,000	$235,000
Benefits	$47,000	$282,000
Computer Costs		$10,000
Travel		$5,000
Rural Organ/Tissue Transportation and other		$20,000
Present operating budget shared by each of two hospitals		$170,000
TOTAL		$507,000

Proposed Function

a. to act as the central contact to receive inquiries from the general public about organ donation and to receive notification of potential organ donors

b. to assist with the transportation of donors and organs

c. promoting public awareness and education regarding organ donation

d. liaison with medical practice, including the development of standards for medical procedures

e. presentation of educational programs to health care professionals

f. maintaining donor registry in conjunction with the Council

CHAPTER 9: ETHICAL ISSUES IN TRANSPLANTATION

The mandate of the Task Force did not include a full examination of the ethical issues of transplantation. However, as is apparent from the main recommendation, the Task Force realised that it is not possible to deal with the societal, cultural and religious aspects of human organ procurement without also being involved with these three aspects of the whole field of transplantation.

It is for these reasons that the Task Force, charged with the task of looking into the question of organ procurement, has recommended a Council in Transplantation, not for example, an Advisory Committee in Human Organs and Tissue Procurement. In so doing the Task Force recognises that the legal and ethical aspects of organ procurement are inextricably interwoven with wider legal and ethical aspects of transplantation medicine, as a whole.

It is incorrect to consider the logistical problems of the shortage of human organs for transplantation as organizational and fiscal, comparable to a shortage of resources and facilities in another branch of medical therapy, such as programs for management of trauma, units for multiple sclerosis or neonatal care.

In transplantation, a term which includes surgical techniques as well as the provision of human organs and tissues, the Task Force sees four avenues of on-going activity:

- a service component confined to organs and tissues,
- responsibility for programs in public awareness and education concerning needs for human organs and tissues,
- an advisory role to Government on transplantation as a form of medical therapy, and
- an Alberta Government supported body under the authority of the Minister,

with responsibility to consider and address ethical and legal aspects in the whole field of transplantation, with authority to evolve responses to public issues as they arise and to conduct programs of public awareness, sounding of opinion and education.

The inclusion of these issues within the responsibility of the proposed Council is based on the Task Force experience that they are the **'whole'** of which human organ and tissue procurement is merely a **'part'**. During the 3 years, the Task Force became repeatedly aware of these wider issues and was repeatedly sought out by the public and by the media (see for example, Appendix Q). Some of the unresolved ethical issues of transplantation are listed below:

1. GENERAL ETHICAL ISSUES IN TRANSPLANTATION

a. **Religious issues in organ transplantation**: Christian, Jewish, Moslem, Hindu, Buddhist, etc.

b. The ethical dilemma for governments in supporting transplant programs; **the ethics of 'conflicting imperatives'**, when resources are limited.

c. Ethical and legal aspects of exchanging organs between different countries, especially when they have wide cultural differences.

d. **Use of the 'media' to promote poorly tested high-profile treatments**, and convert them from research to therapy, without adequate scientific peer review.

e. **Distortion of public perception of health care priorities** by undue media attention to dramatic health care issues, affecting small numbers of people.

f. **How to maintain confidentiality of donors** and recipients in the glare of publicity surrounding dramatic transplant events and media pressure 'for the story'.

g. The ethics of Institutions not adopting positive public policies towards transplantation, yet having transplant programs. [The Ontario Task Force recommended that the Ontario Government direct that Boards of Directors of hospitals should issue policy directives in support of transplantation, and name Transplant Coordinators and/or Transplant Organ Donor Committees.]

h. **Transplant recipient rights and their advocacy.** [The Ontario Task Force recommended that special and unusual recipient costs could be taken up under regulations for 'urgent care', in that Province.]

i. Need to define **the ethics in private for-profit operations** in promoting high-visibility health care projects, leaving the more mundane or more expensive problems to the public sector.

j. Ways of **ensuring equality of access to expensive procedures.**

k. The **philosophical, ethical and legal aspects of commerce in human organs** and tissues obtained from brain dead donors.

2. THE LIVING DONOR OF ORGANS AND TISSUES (esp. kidneys).

a. Living related kidney donors, from family members:

1) **issues in poorly bonded families.**

2) the coercion of the **"HLA-identical imperative".**

3) inter-family live donor exchange contracting, where families without

well matched donors are brought into contact with other similar families with which inter-family mutual exchange would be HLA compatible, with a view to kidney transplantation between such families.

b. Spousal and emotionally related organ donation

c. the **whole issue of altruism in society**, in especial regard to altruistic donation of organs and tissues by living unrelated members of the public

d. donation of tissues and organs by children

e. donation from other legal incompetents

f. **living donors of organs for covert compensation;** the commerce of organ donations from living donors; when does compensation for 'time lost on the job' or compensation for inconvenience become 'payment for the donation'.

3. PROCUREMENT OF ORGANS FROM THE DEAD

a. Equitable Distribution of Cadaveric Organs

1) **who legally owns,** and therefore decides on distribution of *extra corporeal* organs?

2) in relation to processing and transportation fees, **what constitutes the 'sale' of an organ?**

3) how can patients be assured of equal opportunity for transplantation?

4) what should determine relative needs of patients of different parts of society, of the country, or between countries, when all are in

need?

5) how can regional and international sharing of human organs and tissues best be regulated?

6) other issues in the equity of distribution

b. The Issue of Premortem Permission (for Post-Mortem Organ Procurement)

1) **"Opting In" versus "Opting Out" Legislation:** pros and cons; an on-going issue involving repeated sounding of public opinion and public education

2) pre-mortem consent for post-mortem donation:

a) **the best site to record donation consent:** driving license or Provincial Health Care card?

b) non-issuance of driving license or health care card until individuals make a decision with regard to disposition of organs at death. **The question of a mandatory requirement to answer** 'Yes', 'No', or 'Refuse to answer' to a question on this matter, the answer to be recorded on the card. The latter is another on-going issue, which is not yet resolved.

c) pros and cons of Registries; another unresolved issue.

3) for doctors who are looking after a potential brain dead donor, in hospital, there is **the issue of 'required request'** or obligation to ask for consideration by the family of organ donation after death of their relative. An active issue in USA, at present. This is an issue on which the Boards of Directors of hospitals might well have to make decisions.

4) the question of having **an audit of the Organ Donation Rate** in

hospital accreditation. Perhaps, in contemporary medical practice, this is a more important indicator for accreditation than some others, such as the autopsy rate.

5) **the need for a changed professional ethic** to one where all doctors feel a responsibility towards determining dying patients' wishes for disposal of their body.

4. RESPECT FOR THE DEAD, IN A TRANSPLANTATION CONTEXT

a. philosophical/religious aspects

b. medical aspects

c. legal aspects

5. ON-GOING ETHICAL AND LEGAL ASPECTS OF ORGAN STORAGE

These have been addressed in other parts of the Report, but are also perceived as on-going.

The proposed Council is seen as a body which would study these questions through it's committees, public forums and soundings of opinions in order to provide the Minister with sensitive, responsive and expert opinions, on a regular basis, on these important societal, cultural and religious issues.

APPENDICES

APPENDIX A

Members of the Task Force

Mr. Andrew Little, Calgary
Mr. Little is a retired officer of the Calgary Police Force. During his term as Member of the Legislative Assembly for Calgary-McCall, Mr. Little was successful in passing the private motion which led to the creation of the Task Force. Mr. Little also served as the Chairman of the Task Force.

Dr. John C. Butt, Calgary
Dr. Butt is the Chief Medical Examiner for the Province of Alberta.

Dr. Peter Craigie, Calgary
Dr. Craigie is Vice-President (Academic), Professor of Religion and Ethics, and former Dean of Humanities at the University of Calgary.

Mr. John Dahl, Whitecourt
Mr. Dahl is a prominent Alberta businessman who, as a result of a family history of eye disease, has been a long-time promotor of corneal donation and transplantation.

Dr. John B. Dossetor, Edmonton
Dr. Dossetor is Director of the Division of Nephrology at the University of Alberta Hospitals; Professor of Medicine, University of Alberta; Chairman, H.O.P.E. Committee (Edmonton); and a Medical Research Council Career Investigator.

Dr. D. T. R. Hassard, Edmonton
Dr. Hassard is Clinical Professor of Ophthalmology, University of Alberta, Edmonton, and an ophthalmologist whose practice includes the transplantation of corneal grafts.

Dr. John Klassen, Calgary
Dr. Klassen is Professor of Medicine and Pathology, University of Calgary, Chairman of the H.O.P.E. Committee (Calgary), and is an immunologist at the Foothills Hospital in Calgary.

Dr. William H. Lakey, Edmonton
Dr. Lakey, who is Professor of Surgery (Urology), University of Alberta, Edmonton, is a kidney transplant surgeon on the staff of the University of Alberta and University of Alberta Hospitals.

Ms. Joan E. Nightingale, Edmonton
Ms. Nightingale is Manager of Critical Care Services with Alberta Hospitals and Medical Care.

Staff to the Task Force

Janice E. Trylinski, M.Sc., LL.B.
Ms. Trylinski, Medical-Legal Research Co-ordinator for the Task Force, a microbiologist, is also a member of the Law Society of Alberta.

APPENDIX B

ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE TERMS OF REFERENCE

Ministerial Order #31/83
Revised August 16, 1983

The Task Force was asked to report to the Minister of Hospitals and Medical Care in connection with the planning of more effective means for the procurement and utilization of human organs and tissue for therapeutic purposes, medical education and scientific reseach in Alberta and, in particular, to identify and make recommendations on:

a. key issues related to the procurement, storage and utilization of human organs and tissue.

b. programs related to the procurement, storage and utilization of human organs and tissue, for example, the Human Tissue Procurement and Exchange Program, and the proposed Tissue Bank Facility.

c. levels of funding and resources required to implement the programs.

d. standards and operating procedures related to the procurement, storage and utilization of human organs and tissue.

e. the legislation related to the procurement, storage and utilization of human organs and tissue.

f. whatever further study, research and inquiries the Task Force deems necessary to achieve the desired results.

APPENDIX C

SUBMISSIONS TO THE TASK FORCE

Anyone with an interest in the problems of transplantation was welcome to meet with the Alberta Human Tissue Procurement Task Force. Appendix C lists the delegations which met with the Task Force, the invited speakers, observers and presentations at the meetings of the Task Force, letters received from individual Albertans and Albertans who, because of the experience, were asked to become special advisors to the Task Force.

Delegations, Speakers and Presentations

Alberta Community Health Nurses Society

Dr. J.D.M. Alton
#520, 8409 - 112 Street
Edmonton, Alberta
T6G 1K6

Prof. W. Bowker
Professor Emeritus
Faculty of Law
University of Alberta
Edmonton, Alberta

Dr. Stan Boyar
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Bragg Creek, Alberta
T0L 0K0

Dr. N. Boyd
c/o Dr. Shuttleworth
Calgary Diagnostic Laboratories
2504 - 5th Avenue N.W.
Calgary, Alberta

Dr. Lorne R. Buhr, Head
Information and Reference Services
Legislature Library
216 Legislature Building
Edmonton, Alberta
T5K 2B6

CNIB (Alberta Division)
Edmonton, Alberta

Inspector K. Cavanaugh
Calgary City Police
Traffic Division
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Calgary, Alberta
T2G 0J2

Dr. Robert F. Clark
Executive Director
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Dr. G. Cochrane
207, 803-1st Ave. N.E.
Calgary, Alberta
T2E 7C5

Mr. W. Coghill
Edmonton Ambulance Authority
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Edmonton, Alberta

Mrs. Mae Cox
Edmonton, Alberta

Dr. Garry W. Curtis (observer)
Saskatchewan Dept. of Health
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Mr. J. M. Dahl
Whitecourt, Alberta

Ms. Lynn Fester
Admin. Off. to V-P (Medical)
University of Alberta Hospitals
Edmonton, Alberta
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Mr. B. Gilroy
Department of Vital Statistics
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Mr. J. Hendriks, Director
Management Info. Dev.
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Dr. Lorne A. Klippert
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Dr. N. Kneterman
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Edmonton, Alberta

Mr. Ronald Kustra (observer)
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Alberta Medical Association
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Dr. L. E. McGann
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The University of Alberta
Edmonton, Alberta

Mr. Alec McKay
Edmonton

Organ Donors Canada

Dr. H. Pabst
Dept. of Pediatrics
University of Alberta
Edmonton, Alberta

Dr. D. Perry
Misericordia Hospital
Edmonton, Alberta

Physicians of the Drayton Valley General Hospital
Drayton Valley, Alberta

Mrs. Anne Russell
(formerly of the Planning Secretariat)
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Social Services & Community Health
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Dr. Dean Sandham
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841 Centre Avenue E.
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Ms. Darlene Schindel, R.N.
Station 22, Royal Alexandra Hospital
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Edmonton, Alberta

Ms. Marjorie Smith, R.N.
I.C.U., Foothills Hospital
Calgary, Alberta
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Mr. Bernard Starkman (observer)
Room 642, Justice Bldg.
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Ms. Betty Tomte, R.N.
Assistant Registrar, A.A.R.N.
10256 - 112 Street
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1983 Class of Christian Theology 352
St. Joseph's College
University of Alberta

Other Submissions to the Task Force

Various private citizens.

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Special Advisors to the Task Force

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Dr. A.R. Turner
Cross Cancer Institute
University of Alberta Hospital
Edmonton, Alberta

Physicians Interviewed in Preparation of the Task Force Report

Dr. J.D.M. Alton, Edmonton

Dr. R.J. Bailey, Edmonton

Dr. Birdsell, Calgary

Dr. Bissel, Edmonton

Dr. B. Campbell, Calgary

Dr. Lyle Davis, Edmonton

Dr. Dawson, Red Deer

Dr. E. Gelfand, Edmonton

Dr. Greenhill, Edmonton

Dr. John Huckell, Edmonton

Dr. H. Hyde, Edmonton

Dr. Kostiuk, Edmonton

Dr. L. McGann, Edmonton

Dr. W. Newcastle, Calgary

Dr. Procyshyn, Edmonton

Dr. Ray Rajotte, Edmonton

Dr. Riyal, Edmonton

Dr. J. Russel, Calgary

Dr. N. Schachar, Calgary

Dr. Sinton, Red Deer

Dr. Turner, Edmonton

Dr. Wakefield, Red Deer

APPENDIX D

Papers Presented at the International Symposium on Organs for Transplantation

May 22-25, 1985, Lake Louise, Alberta

Session I: Medical Progress and the Human Soul
"Medical Progress and the Human Soul", by Malcolm Muggeridge.
"In Defense of Science and the Soul", by Gary Friedlaender
"Live Donors, Related and Otherwise", by Maurice Slapak

Session II: Ethical Issues In And Around Transplantation
"The Ethical Continuity of Transplantation", by Benjamin Freedman
"Freedom to Choose and Freedom to Lose: The Procurement of Cadaver Organs for Transplantation", by Barry Hoffmaster

Session III: Legal Considerations in Human Organ Transplantation
"Commerce in Tissue and Organs", by Gilbert Sharpe
"Inter Vivos Transplantation: The Child and Dependent Adult as Donors", by Bernard Starkman
"A Legal Definition of Death - Can it Affect Supply of Tissues and Organs?" by Edward Keyserlingk
"Procurement vs. Donation of Tissues and Organs for Transplantation: Should 'Contracting Out' Legislation be Adopted?", by Margaret A. Somerville
"A Human Rights Perspective on Donor Legislation", by Christopher D. Evans
"The Organ Donor Card in Alberta Is Not A Will", by Wilbur F. Bowker
Panel Discusssion on Legal Issues

Session IV: New Ideas and Techniques for Vital Organ Procurement and Exchange
"Organ Procurement in Munich: Financial and Organizational Aspects", by Walter C. Land
"The Non-Physician Coordinator's Contribution to the Development of an Organ Procurement Program", by Donald W. Denny
"New Ideas and Techniques for Vital Organ Procurement and Exchange", by Maurice Slapak
Panel Discussion on Vital Organ Procurement and Exchange

Session V: Organ and Tissue Storage: Present and Future
"Bone Banking and Clinical Application", by Gary E. Friedlaender
"Eye Banking, a Growth Story", by Charles R. Graham Jr.
"Cryopreservation of Skin - A Review", by Charles Baxter
Panel Discussion on Tissue Banking

Session VI: Transplantation and the Allocation of Health Care Dollars
"The Socioeconomics of Organ Transplantation", by Roger W. Evans
"New Organ Transplant Program - The Decision Tree", by Joan E. Nightingale
"Resource Allocation: A Medical Research Field", by Lionel E. McLeod

APPENDIX E

"Malcolm Muggeridge - Medical Progress and the Human Soul"

and *"A Lake Louise Postscriptum"*

Videotapes from

International Symposium on Organs for Transplantation
May 22-25, 1985

Lake Louise, Alberta

Produced and directed by D. K. Spence
With editorial assistance from J. E. Trylinski
Technical assistance by Lawrence Benson

An edited videotape of Mr. Muggeridge's keynote address and post symposium remarks has been prepared and is available from:

The Department of Radio & Television
CW-005 Biological Sciences Centre,
University of Alberta,
Edmonton, Alberta, T6G 2E9
(403)-432-4962

The two presentations are included on one 60 minute cassette, available in VHS, Beta or U-matic format at a cost of $100.00. A broadcast version of "Medical Progress and the Human Soul" has also been prepared, length 28':50".

For information regarding broadcast rights please contact:

Donald K. Spence, Producer,
Dept. of Radio & Television,
CW-005 Biological Sciences Centre,
University of Alberta,
Edmonton, Alberta, T6G 2E9
(403)-432-4962

APPENDIX F

ALBERTA H.O.P.E. PROGRAM TRANSPLANT STATISTICS

	Cornea Transplants Calgary	Edmonton	Total in Province of Alberta
1981	18	30	48
1982	46	33	79
1983	54	84	192
1984	76	114	190
1985*	41	61	102
	Kidney Transplants		
1981	14	23	37
1982	22	34	56
1983	26	40	66**
1984	28	34	62
1985*	15		
	Bone Transplants		
1981	3		
1982	3		
1983	2		
1984	0		
1985*	2		

CNIB, Northern Division, Edmonton

Albertans and Corneal Tissue, Statistical Information

	Corneal Transplants Performed	People Waiting
1981	46	215
1982	76	262
1983	124	253
1984	186	262

* To June 30, 1985

**Note that the Canadian Renal Failure Register 1983 Report, published by the Kidney Foundation of Canada, states that the number of kidney transplants performed in Alberta in 1983 is 68 (see Table 31, page 77).

APPENDIX G.1

Public Opinion Poll

Responses to published Advertisement

A total of 37 individual responses and two group responses to the advertisement were received. A sample of this size is not large enough for statistical analysis, but a general overview of response trends was of assistance to the Task Force.

I. INDIVIDUAL RESPONSES

Question 1: Where do you stand on the subject of organ and tissue transplants?

Those persons responding to the advertisement were almost universally in favour of human tissue transplants. One writer expressed some concern about high costs and difficult ethical issues in some cases, and another writer was unwilling to make a donation herself and thus, perhaps, felt reluctant to indicate support of transplantation in general, but it appears safe to assume that Albertans are largely in favour of transplants taking place.

Question 2: Should the decision to donate or not be mandatory or voluntary?

This question appeared to have been construed in several ways by those responding to the advertisement. Generally, the respondents interpreted the question as seeking their opinion on what is referred to as opting out versus opting in systems. Approximately six of the 37 respondents appear to be in favour of the opting out system where consent to donate is implied in the absence of express refusal. Two respondents felt that donations should be mandatory for automobile accident victims. One favoured implied consent (opting out) in all cases of post mortem donation. One respondent interpreted the question as whether or not individuals should be forced to make a choice between donation or non-donation and took the position that the choice itself should be mandatory.

Clearly this remains a contentious area and suggests that the majority of Albertans would not be in favour of mandatory donation or even of implied consent to donation in the absence of express refusal.

Question 3: Should the next-of-kin have the right to alter a donor's wishes?

Only five of those individuals responding to the advertisement felt that an individual's decision to donate should be subject to alteration by relatives. The general sentiment expressed was that every individual ought to have freedom of choice to make the decision to donate and, the decision having been made, it must not be altered by any person. One respondent did feel that, where a deceased person had given no indication on donation, close relatives should have the right to make that decision for them in the event of their death.

Question 4: Should the driver's licence donor card system be replaced by a computer bank? How should the new system operate?

This question brought forth the widest variety of responses, with most people indicating that they were not overly knowledgeable in this area. Most respondents

felt that the present driver's licence donor card system was a step in the right direction but that more was required. Several suggested that the present system be computerized to expedite information access. Many expressed concern over the fact that some persons may not possess or carry a driver's licence and suggested instead that donation be administered via the Alberta Health Care system with the donor cards being part of the Alberta Health Care card. Several respondents expressed concern over the possibility of computer abuse. Apparently there exists a relatively widespread belief that, were an individual's decision to be stored in a computer, that decision could be inaccurately recorded or altered by unscrupulous persons. One writer expressed concern over whether doctors and family members can be relied on to carry out their wishes while another felt that many individuals might view systematic recording of a decision to donate as likely to induce bad luck.

II. GROUP RESPONSES

Two groups of medical personnel within the province responded to the advertisement, Physicians at the Drayton Valley General Hospital and the Alberta Community Health Nurses Society.

Physicians at the Drayton Valley General Hospital

Question 1: Where do you stand on the subject of organ and tissue transplants?

All ten physicians responding were of the opinion that tissue and organ transplants were desirable and that research should continue.

Question 2: Should the decision to donate or not be mandatory or voluntary?

All ten physicians were of the opinion that the decision to donate should be entirely voluntary.

Question 3: Should the next-of-kin have the right to alter a donor's wishes?

All ten physicians were of the opinion that the next-of-kin should not have any right to alter a donor's wishes (when made voluntarily) but that every sympathy must be accorded to the recently bereaved and that every effort should be made not to add to this sorrow.

Question 4: Should the driver's licence donor card system be replaced by a computer bank? How should the new system operate?

All ten physicians were of the opinion that the present driver's licence donor card is a simple, cheap and effective method of indicating one's wishes especially in country districts where access to a computer may be difficult. However, the physicians suggested that both systems might be able to co-exist. Opinion was mixed, however, over the way in which such a system would operate; five physicians thought drivers should be permitted to get into the donor group; four physicians thought that all drivers should be assumed to be donors unless they actively opted out of donation; and one physician had no opinion.

In general, the physicians were of the opinion that the topic required more publicity.

Public Opinion Poll ... continued

Alberta Community Health Nurses' Society

The Alberta Community Health Nurses' Society polled its membership by including the questionnaire in its newsletter. Approximately 300 questionnaires were sent out and 53 were returned.

Question 1: Where do you stand on the subject of organ and tissue transplants?

Forty-four were in favour of transplants.

Question 2: Should the decision to donate or not be mandatory or voluntary?

Fifty-two believed that the decision to donate should be voluntary; seven believed it should be mandatory.

Question 3: Should the next-of-kin have the right to alter a donor's wishes?

Forty-seven were of the opinion that the next-of-kin should not be able to alter a donor's wishes; six were of of the opinion that the next-of-kin should have this right.

Question 4: Should the driver's licence donor card system be replaced by a computer bank? How should the new system operate?

Thirty-two indicated that the driver's licence donor card should be replaced by a computer data bank and twenty-one indicated that no change was necessary.

APPENDIX G.2

A SUMMARY OF THE ONTARIO TASK FORCE REPORT ON KIDNEY DONATION DECEMBER 2nd - 4th, 1984

John B. Dossetor

This is a summary of the Ontario Task Force symposium under the title "Organ Donation in the Eighties: a Blueprint for Success". The mandate of this Task Force was to look at barriers to renal transplantation in the Province of Ontario. As such, the mandate was more limited than that of the Alberta Task Force, but their efforts provided very valuable data about transplantation in that province, some of which may apply to Alberta.

This summary is based on the Committee Reports to the Ontario Task Force distributed at the December 1984 meeting of the Task Force. These documents were later used for the final report to the Ontario Government. They are also being published in *Transplantation Proceedings* at the same time as the Alberta Task Force, Lake Louise Symposium.[19]

I. DONOR IDENTIFICATION

The first section of the "Blueprint for Success" material was a report of the Donor Identification Committee, whose mandate was to look for the factors which trigger or prevent organ donation. Intensive Care Units (ICUs) were asked to respond to a questionaire, which was also sent to 60 neurosurgeons and 121 neurologists. A different questionnaire was also sent to hospital adminstrators.

In hospitals with a renal transplant program, 93% had an organ donor policy, but such a policy did not exist in 55% of all Ontario hospitals, also 54% of hospitals did nothing actively to promote organ donation. In 83% of non-transplant hospitals there was no individual responsible for co-ordinating organ procurement. **Factors responsible for not procuring organs (according to hospital executive officers) were: a) lack of interest by medical staff or medical board, b) failure of reimbursement of the hospital, and c) absence of outside stimulation.**

The survey within ICUs revealed that physicians and nurses are the persons who usually initiate organ donation. This is seldom due to the finding of a signed donor card, though this has been a factor on several specific occasions.

Only 45% of health professionals were aware of phone number to call, in the event of a potential organ donation. The large majority favoured a regional over a provincial phone contact point.

To the questions on the sort of medical aspects which would indicate a potential donor, there was a large measure of accurate knowledge: donors were recognised as needing to be relatively young, without malignant disease or systemic infection or hepatitis. Most responders realised that being over 50 years of age, hypotension or fever did not rule out the possibility of being considered. Failure to recognise the correct type of patient is apparently not a barrier.

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[19]Supplements to the December, 1985, issue.

Most said that the commonest barrier was the refusal of the family to give consent, though other important factors were unavailability of family and lack of support by physicians. Lack of support from hospital adminstration or from the coroners was NOT a problem. However, if administration had clearly supportive policies, these might help very considerably with the non-supportive physician.

The donor identification process was not a positive experience for over 50% of those who responded.

II. THE DONATION PROCESS

This committee focused their attention on:

1. programs for increased public awareness of recipients' needs, as part of the responsibility of the Provincial Organ Donor program;
2. the suggestion that there be a central registry of donors who have signed a card (be it the driving license or some other form);
3. the need for all secondary and tertiary hospitals to have an Organ Donation Committee;
4. the need for each such hospital to provide a donor assessment consultation service;
5. the need for regular hospital audits of deaths and organ donation;
6. the need for each main hospital to have Board of Directors' policies to implement some or all of these recommendations.

A survey was carried out in 5 hospitals. For Toronto General Hospital the survey was for 1981 and 1982. Surveys for one year only were carried out for the Sunnybrook Hospital, Toronto, the North Bay Civic Hospital, St Joseph's Hospital, North Bay and St Mary's Hospital in Kitchener Waterloo. Deaths in these hospitals ranged from 148 to 1087 in a given year. Potential donors were assessed at 2.3% and 3% in TGH, and up to 6% in St Mary's. The percentage of potential donors who were missed was 44% and 45% in Toronto General Hospital, 61% at Sunnybrook, 75% at North Bay Civic and 80% at St Mary's. They believed that the Ontario Hospital Association should provide hospitals with guidelines for the identification of potential donors, using the vehicle of the Organ Donor Committee at that hospital for their dissemination.

III. CONCLUSIONS ON DONOR IDENTIFICATION AND THE DONATION PROCESS

Factors which might stimulate the donor procurement process were:

- educational seminars at the level of medical student, resident, nurse in training, nursing staffs of special units, attending medical staff and hospital administration
- repeated reminders of on-going recipients' need by various in-hospital and within-profession communication systems
- attention to the economic 'barrier to transplantation' (where, currently, there is much professional work being done without any compensation)
- the naming of a Transplant Organ Donor Coordinator at all hospitals which have an ICU, and a Transplant Organ Donor Committee at all large general hospitals
- a widely known regional Transplant Donor phone number
- a Board of Directors Hospital policy in support of transplant donation
- Government reimbursement policies for donor hospitals, for those extra expenses incurred by the donation process
- positive feed-back from transplant centres to donor-providing hospitals.

IV. BRAIN DEAD DONOR TRANSPORTATION

The recommendations in this area are relevant to certain costs which also occur in Alberta.

The principal conclusions, after an extensive review of the different hospitals' problems, were that OHIP should cover the following costs under the recipient's OHIP plan:

- recipient transportation costs, under the terms of 'urgent care',
- the transport costs of donors, including costs of transport of out of province donors
- the cost of returning the donor's body to it's home for burial, including returning the body of donors from out of the Province,
- the transportation costs of the organ retrieval team.

They did not address the costs of transport of a brain dead donor to the Transplant Centre if subsequently there was no organ donation.

V. THE PROCESS OF ORGAN RETRIEVAL AND DISTRIBUTION

This part of the work of the Ontario Task Force was subdivided into Institutional, Professional, Technical and Immunological.

They provided data in a number of areas, as condensed below, and then drew conclusions from them. They observed that:

1. Of the 90 or so donors each year in Ontario, 87% are patients who died in the tertiary care hospitals. This could mean that those who die in smaller

peripheral hospitals do not have conditions that make them potential brain dead donors, or that they are suitable but do not become donors because of the increased number of barriers to transplantation, from such sites;

2. The cost of maintaining a donor of vital organs is about $4,200 (ranging from $2600 to $5900 per donor). The cost per organ would be dramatically reduced if multiple organs were used from a single donor. There is no existing mechanism for institutional reimbursement of these expenses.
3. Three professional barriers were examined: clinical expertise, professional remuneration, and the 'time spent' factor (for those in charge of potential donors). There were problems in all three areas: many doctors do not know who or how to contact the transplant services. Of the $1,440 paid out in fees for each renal donor, the neurosurgeon (who is critically important to procurement) averaged $79.00. The 'time spent' in obtaining permission was identified as a major disincentive, also;
4. Although in Canada only 40% of kidneys were cold-stored, this figure was only 27% in Ontario. 60% of kidneys for Canada outside of Ontario used cold storage. This method is far cheaper than machine perfusion. In an analysis of over 36,000 transplants, from the medical literature, cold storage was found to be superior in terms of 1 year graft survival to the more expensive machine perfusion (for ischemic times of up to 48 hours). This is also true for 2 smaller prospective studies, one in Australia and the other in Canada. It is much cheaper per kidney to carry out cold perfusion (less than $100) than machine perfusion ($100-$1400) per kidney);
5. Unless there is an attempt made to give kidneys to those centres which contribute them to the pool, in Ontario, a disincentive is created. This is deleterious to overall graft survival which shows beneficial influence from both close matching by tissue typing and other cross match methods (which imply one should use as large a pool of potential recipients as possible);
6. Calculation was made of the costs of retrieving and distributing one cadaver kidney, as follows:

Donor support	$1500 - $2,144
Professional fees	$ 662 - $ 822
Preservation cost	$ 113 - $ 809
Transportation cost	$ nil - $1,500
Tissue typing	$ 106 - $ 106
Crossmatching	$ 543 - $ 543
TOTAL	$2924 - $6194.

7. The kidney transplant rate was 25/million/year (1981-83) in Ontario, but only 20/million/year for Canada as a whole. Of these, 81% received kidneys from donors who were nephrectomized in their own medical centre;

Editor's note: This transplant rate of 20/million/year may be put into better context by the following additional statistics:

Incidence of Chronic Renal Failure (CRF) = 60/million/yr
Need for transplantation of new CRF patients = 50/million/yr
Present demand for transplantation of these new CRF patients = 40/million/yr.

Thus the overall transplant rate is equivalent to 40% of new CRF patients/yr.

This does not give a true picture as it ignores the accumulated CRF patients from previous years, who have accumulated in CRF programs.

Thus the transplant rate of 20/million/yr is taken from the patients of many years accumulation. In Edmonton, this accumulation of CRF patients numbers 250 per million, of whom just over one-third have been transplanted.

As the death rate on CRF programs is only 10% per year, it is clear that programs are gradually increasing in number. In Canada, at present, this accumulation **(the actual prevalence of CRF)** has increased to about 250 patients/million. Because of the low death rate (or high success rate for management of CRF) it is expected that prevalence will go on increasing (without a change in incidence) until the death rate offsets the incidence. At this point it is estimated that there will be 700-900 patients/million in CRF programs. As the annual cost of maintenance on dialysis ($30,000 per patient) is 3-5 times that of management of a successful transplant ($8,000 per patient), there is a very significant saving of health dollars if the transplant rate is much increased. This is indeed fortunate as most authorities also recognise that renal transplantation gives a better quality of life for CRF patients. In the USA, current annual expenditure for CRF is $2 billion.

8. In the USA transplant programs, there were 45 kidneys/million of population, though it is not clear if this applies only to the population served by the centres surveyed, or to the whole of the USA.

The following conclusions were made for increasing organ procurement:

At the Institutional (Hospital or University) level:

- uniform educational policy throughout the province
- identification of secondary and tertiary centres as suitable for donor support and organ donation, and that these functions be mandated of them as a clinical care responsibility,
- suitable ways of institutional reimbursement be devised through a government program,
- development of hospital policies to support transplantation,
- hospital medical audit to include organ donation rates.

At the professional level, it was concluded that the need was for initial assessment of a potential donor to be considered as an important medical service, including the introduction of the concept to the family, and be appropriately recognized in the medical fee schedule. It was also recommended that a Regional Donor Support program be established to take care of the non-living donor, immediately on notification from the referring physician, and that this service be funded by Government.

At the technical level, it was recommended that a uniform method of handling of kidneys, ex vivo, be adopted for storage and transportation, and that the cold flush rather than the continuous perfusion systems be adopted.

At the immunological level, it was proposed that two essential services, tissue typing and immunological cross matching, be incorporated into the regional service so that their findings can be used in distribution and other decision-making.

Organisation for kidney distribution. This is perceived as a special problem in Ontario, where there are 9 transplant centres and where there is a strong desire to see kidneys distributed back to those regions which supply most, and yet also to take into account the principles of immunologic matching as well as the exigiences of urgent medical need, etc. (*Editor's note*: There is no comparable problem in Alberta, but it would become one if a system was developed which crossed the boundaries of Western Provinces).

VI. GALLUP POLLS ON DONATION AWARENESS AND COMPLIANCE

A comparison was made between the Gallup Poll carried out in the USA and a similar one in Canada. In the US one, 72% were aware of organ transplants and said they would give organs of loved ones, 50% would give their children's kidneys, but only 24% said they would want their own kidneys donated, after their death. Fear of mutilation seemed to be a factor.

In Canada, it was possible to compare 1978 with 1983. In 1978, 12% had signed the card. By 1983, this had risen to 21% and there was 38%, in all, who said they were willing to sign even though this additional 17% had not done so.

Eight-eight percent said they would respect the donors wishes, if this were known. In the last Canadian study, 63% said they were willing for their kidneys to be used for transplantation after their death, but about 1/3 persons said they were not willing to sign their cards.

APPENDIX H.1

SUMMARY OF TESTIMONY PRESENTED AT THE MEETING OF THE ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE ON DONOR CARDS AND DONOR REGISTRIES EDMONTON, ALBERTA, JUNE 20th, 1984

Inspector K. Cavanaugh
Calgary City Police, Traffic Division
Calgary, Alberta

Inspector Cavanaugh is a supporter of organ donation and he provided the Task Force with background information on the role of the police in accident investigation and organ donor identification. He made the following points:

- The police do not routinely check for donor cards when they are dealing with a serious accident. Their concern is to get the person to hospital. They allow the ambulance service to remove the injured person and get him to the hospital. At that point the police may not even know the identity of the injured person.
- Following a letter from the Chief Medical Examiner in 1979 regarding cornea donation, a procedure was put into place to notify a Medical Examiner when a donor card is located at an accident scene.
- It is inappropriate on the part of the police to ask the next-of-kin to consider organ donation when they are notifying the next-of-kin of a fatality. (Inspector Cavanaugh expressed further doubt about the propriety of a person in authority in uniform making such a request.)
- With regard to obtaining family permission for organ donation, it can often take the police four or five hours to locate the family. With younger people police often experience great difficulty in locating any family member. About one third of the violent deaths last year had next of kin from out of province, but the majority of them are from the East.
- There were fifty-five fatalities in Calgary last year and no signed donor cards were found. There were eleven fatalities this year and one was a donor but it is not certain if that was through a driver's licence organ donor card as the donor was seriously injured and taken to the hospital on life support.
- If a procedure for routine determination of the donor status of a victim was developed it would be possible to put driver's licence donor card information into a computer so that it could be accessed immediately, from the car through police information channels.
- The police force could handle organ donation provided that it was developed so that they could take a professional approach to it, knowing that they would have co-operation from all concerned.
- Professional education regarding donors and donor cards could be easily worked into the police training process.

Recommendations for improvement of the organ procurement system:

- A central service that is easily accessible would be useful and donor information on a central computer would be ideal.

Mr. W. Coghill
Edmonton Ambulance Authority
Edmonton, Alberta

Mr. Coghill is the General Manager of the Edmonton Ambulance Authority and President of the Ambulance Operating Association of Edmonton. Mr. Coghill had a personal experience with transplantation in that a family member who died suddenly with organs and tissue suitable for donation was not considered for donation because of hospital policy. Mr. Coghill is in favour of mandatory donation of organs but recognises that this view is not shared by the general public. He provided the Task Force with essential background information on the operation of the ambulance system in Alberta, the different levels of ambulance service and the differences between urban and rural ambulance service. He made the following points:

- There are many potential donors other than the motor vehicle accident victims. In most circumstances, in the violent motor vehicle accident death, the majority of organs are not viable for organ transplant.
- The ambulance operator has access to victim ID but in the circumstances of sudden death probably 90 percent of the patients don't have any identification on them, or at least do not have a driver's licence on them.
- Even when the ambulance service has access to the victim's ID it may not be tactful for the ambulance service to ask about organ donor cards.
- There are no consistent patient report forms in the province and potential donors are not brought to the attention of the emergency department.
- There is a major difference between inner city and suburban or rural accident situations. In a smaller centre, the majority of patients will be pronounced dead immediately. CPR will not be continued because of manpower restrictions. Not all hospitals have mechanical cardio-pulmonary resuscitation devices in order to maintain effective CPR on a particular victim and thereby maintain organ viability. In a small rural hospital, where there is one physician the approach to the victim is different to a major urban centre with transplant facilities. The rural accident situation automatically reduces the potential for people reacting to viable donors. In the major urban centres there are more potential donors.
- Levels of ambulance service can affect the viability of organs for transplant. Many potential organ donors will never donate because of sub-optimal care in the field. Manual CPR skills may be poor. When pulse and respiration are deteriorating rapidly (especially in the rural areas) they may not be maintained and one may start losing the patient during transport. When that happens the potential for organ donation is lost.
- There is no consistent approach among ambulance services in the province to provide advanced life support tactics on patients that are potential vital organ donors.
- Few ambulance operators are aware of organ donation problems or programs in the province of Alberta.

- There's no hospital procedure in place to determine whether resuscitation measures will be used or whether the patient will be maintained until organ donation has been discussed.
- A strengthened citizen CPR training program will provide more donors.

Recommendations:

- Team oriented training programs which explain critical post-mortem times for vital organs, non-vital organs and tissues.
- A co-ordinated educational program so that the ambulance operations do not encroach on the police department's operations.
- Ambulance services should be kept informed of the need for organs in the province of Alberta by a central registry for required organs and regular mailings to hospital emergency departments.

Mrs. Anne Russell
Legislative Planning, Social Services & Community Health
Edmonton, Alberta

Mrs. Russell is personally in favour of opting-out legislation but is of the view that it should not be considered without exploring alternatives such as better public education. Mrs. Russell advocated a donor registry and made the following points:

- A registry would provide a central point for physicians and hospitals to determine the status of a donor. Access to the information must take place as quickly as possible when one has a donor. The best way of getting that information is by telephone and not by scrambling around the patient's belongings or asking him if there is a card or if a decision has been made.
- The registry provides a way of avoiding the traumatic question to the family. In the process of building up the registry, there should be a requirement that the patient have his donation witnessed and preferably that he have it witnessed by a member of the family. If the patient who is making a donation is required at the time of making the donation to explain it to his family to make them aware of his wishes and actually having them sign as a witness it may relieve the physician of a very difficult task.
- In order to get around the problem of using drivers licences, which are rather limited in scope, cards could be mailed to every head of the household (that the Alberta Health Care Insurance Plan provides the best access in this province to residents and the most complete, up-to-date information in terms of addresses and so on). There are already mailouts that are customarily done by Alberta Health Care Insurance because of the premium. It's possible to add donor cards for a donor registry to that mailout. This would reduce the cost. The card would be received by an individual in circumstances where they have the time to consider whether or not this is the kind of decision they would like to make, and where they were in a situation in which they have the time to discuss it with their immediate family members. It would permit the family to be made aware and to give the family member the opportunity to sign that card as well.
- This stamped, self-addressed card should be mailed to the central registry which would maintain, on the computer, the list of potential donors. This would be accessible by hospitals and physicians throughout the province on a

twenty-four hour basis. Even if a donor registry system was in place patient identification remains a problem, an identifier in the form of a stick-on on the back of the watch might be more readily accessed by people in the emergency ward. The card could serve as an additional identifier to backup the central registry.

- If reverse-onus legislation (such as that in Saskatchewan with respect to corneas) is considered, a registry would still be needed to ascertain those patients who have opted out; who make a decision against donation.
- It is not enough to send out cards without explanatory documents, or to do it only once, it must be done routinely. These things have to be monitored in a way that the motor vehicle licences are monitored with varying degrees of success in North America.
- It would be very hard to legally enforce a requirement that a person to send back the card either saying "Yes, I will", or "No, I won't", or "Don't send me another card," before a person could get the Alberta Health Care Card.
- If the periodic regular mail out puts the onus on the person, once he's made the decision to donate, to let the registry know if he has any change of heart on the subject, one could quite safely rely upon his initial decision. In other words, once he's made a decision to donate, one could assume that in the face of failure on his part to retract that consent, there would be continuing consent as long as it was coming to his attention every year or every five years. With only one mail-out and no contact with the individual again ever, the situation could become very difficult.
- With a registry in place the resulting situation would be the same as the registration in Saskatchewan, because the doctor can assume that he can go ahead. It is not a matter of asking the family for their permission; it is the matter of letting them know. It it is important from a social point of view to ensure that the family is made aware of the donation, but it is not a matter of going to them for their consent because the consent has already been obtained. This would apply to corneas and all organs.
- Confidentiality is a potential problem, but it can be dealt with by legislation, and also on the donor card itself, by providing that other people will be informed of this decision.
- The whole principle of informed consent has not been applied in the case of human tissue donation. It's a principle which applies to the live person, with consent down on paper. Whether that principle would be extended to organ donors is uncertain. But, even under the present system, it is wise to ensure that people making decisions are provided with sufficient information, although it is doubtful that the courts would extend the principle.

Mr. J. Hendriks
Director, Management Information Development
Hospitals and Medical Care
Edmonton, Alberta

Mr. Hendriks, a hospital administrator by profession, is Director of the Information Systems Development Branch for the Department of Hospitals and Medical Care, Government of Alberta. He was responsible for the registration systems and payment systems in medical care programs in other provinces, and is familiar with registration structures and payment structures. He provided the following information:

- The health insurance registration system is the probable place for a donor registry, but it may not be the place to start doing the registration.
- The health care registration system in Alberta is not efficient or sophisticated enough, in terms of on-line capacity, to be able to access it directly. Extensive changes would be necessary and would have to be done over time. With registration system changes in this size of a province, the cost is a few million dollars for the project.
- The health insurance system is a natural place to have a registry because basically everybody in the province is on it, but right now the structure of the system is sequential and, even if we could put the sequential file on-line, the quality of access with respect to it is random and quality is not available. It needs more investigation. Also, because it is an overnight computer, it's just useless in it's present form. It is a big file. Day to day support is expensive, about $400,000 to $500,000 a year.
- If the registration system is a file of 40,000 or 50,000 people, it is best to deal with it on a common basis, without getting involved in other files or systems.
- Fundamental changes are required to bring the driver's licence donor card to the attention of the individual. Some form of communication that will stand out, either by mail, or verbally, depending on how you apply for your licence is required.
- The motor vehicle registry is an on-line, immediately accessible, and randomly accessible, updated verbal system. Changes can be made immediately; it doesn't take three to four weeks to update. It would need significant changes - it's got to become an active system where a person can respond and he wants to be registered.
- For people who aren't on a registry, who don't have a driver's licence, adults, teenagers or children, a separate stand-alone system could be used. You could set up a little file, even use a microcomputer, depending on how many people you think are going to be on it. The mechanism would depend on the volume. Today's microcomputers can hold a significant volume of registration, name, address, donor - yes/no, age. A combination using the motor vehicle registry because it is a good modern file, then setting up a portion that's separate is a possibility. Accessing a further file such as the Department of Education student registry file should also be considered. Teenagers in high schools could be registered through that file, even if there's some redundancy as a result.
- Consent for donation could be registered in more than one place. The main problem is not which system you use to do the registration, but how to keep it updated. With health care insurance, there's no major incentive to register a change of address once you have the card.
- There are many kinds of registration systems in North America and you shouldn't restrict yourselves to looking at tissue donation and registration systems when you want to find out what kind of registration systems are in existence.
- Some of the studies done in the province of Nova Scotia when redoing the registration system showed that the error factor on that file was incredibly high. The error factor for addresses was usually in the 50 percent range, and the error factor in terms of deaths and people who move out of province was 25 percent. That's very significant. I'm sure the Alberta file is no different. It is probably worse because we have a more transient population.
- The only effective file in Canada is in the province of Quebec where systems are all on the same data base. Social services, pension plans, welfare programs, family allowance, health care are all on the one data base and

anybody that changes anything for any of the systems automatically updates all the other files, so that it stays reasonably accurate.

- The motor vehicle registry is reasonably accurate since people can get in trouble if they don't advise of a change of address. You can then use your own system and do some regular mailouts for the balance of the registration file. With a separate structure, your chance of keeping it accurate is better.
- Four hundred thousand (editor's note: estimated potential donors) is not that big a file. It's certainly less of a problem than having to check 2,000,000 people if you decided to keep up your own file. Even the mailing costs are astronomical when you're trying to do this. The major reason Nova Scotia didn't build a new system was not because of the systems development cost but because of the mailout cost. A million dollars was involved, just mailing material back and forth between the registration program and the population.
- It's not particularly important whether you have one system or half a dozen; the fact is it doesn't take very long to access two, three or four systems, but to give every hospital the ability to access half a dozen systems from computer terminals is not sensible. The network costs are expensive, on-line costs are expensive and you've got to have a line that's up and a data base that's up and always accessible. It's easier to keep a central office, where you call in with a zenith number or a WATS line or a 116 number. This gives you better quality control as well, with a group of trained people who know how to access the various systems which you're using for registration files.
- If a person is not on a register, the physician should speak to the family or immediate relatives just as is done now. But it is still important to get away from having to obtain the patient's wallet to check his driver's licence for a card. It it's obvious from the statements by the police department and the ambulance group that this is not something that they do immediately or that's easy to do; so, there has to be another way. Everybody has to be on your registry one way or another but that's going to be only as good as the advertising campaign you use to get to the population.

Mr. B. Gilroy
Department of Vital Statistics, Government of Alberta
Edmonton, Alberta

Mr. Gilroy has experience with an online system of registration for vital statistical events in Alberta. He provided the Task Force with information on a handicap registry in the province of B.C. which is expensive to operate and expensive to update.

- From our Vital Statistics point of view, if our system of keeping the files updated on who's dead this month could add consistancy to keeping your registry updated, you are welcome to it! There wouldn't be any costs, but it is limited to events in Alberta. If a registrant lived here but died outside of the province, we might find out or we might not. Notification may take months. An independent registry may not be necessary. You have more control over it but you have a lot more cost.
- Our source of death occurences is from our own registration forms, often completed in hospitals, but these registrations do not come from, nor are they linked to, the hospitals' system computer. You could die in a hospital and vital statistics wouldn't know.
- You may not want to check your system more than every three years but you

have to sort of weigh how much inaccuracy is there. In other words the problem is if you've got the wrong address your're not going to get to the information in the first place to correct it.

- If registry consent is relied on as the only consent to take the vital organs, then you are legally obliged to have a unique patient identifier. You need something that would assure you that this person is, in fact, who he says he is or who you think he is.
- Today the error factor is a problem that is pretty small; at a guess, probably less than one percent. The ramifications of using a file for your information, cost/benefit complexities, the address problems, the accuracy problems could be answered by an analyst.

Comment: These problems are a part of a ten to fifteen year transition to the point where everybody has made a decision about organ donation. It will then be much easier to look in a standard place to find this answer. There are other ways to do it rather than the AHCIP number. If someone's willing to legislate that you will not be insured unless you indicate your wishes regarding disposition of your body, for example, the answer would surely be obtained. This would be easiest when the person is applying for the insurance in the first place.

Recommendation:

- A good advertising campaign, an active information process and a system which requires reporting "Yes", "No", or "I don't want you to know".

APPENDIX H.2

Police Community Survey

1. Does your Province have the human organ Donor Card attachment to the Driver's License?

2. Does your Police Force have any written or stated policy regarding human organ donor cards?

3. If not, would you be prepared to introduce appropriate policy?

4. Are the ambulance services in your jurisdiction familiar with the human organ donor card?

5. Do you have any suggestions to improve the Donor Card Program?

POLICE COMMUNITY SURVEY

Police Department	Cards attached to Driver's Licence?	Stated Policy?	Would Introduce Policy?	Ambulance Service Aware?	Suggestions
Halifax	Yes	Yes	No	Yes	Bracelet
Moncton	Yes	No	Yes	Yes	Media Coverage
Fredericton	Yes	Yes	N/A	Yes	Education
Saint John	Yes	Yes	N/A	Yes	Advertising
Hamilton-Wentworth	Yes	Yes	N/A	Yes	Education
Quebec City	Yes	No	Yes	Yes	Licence Plates
Quebec Provincial	Yes	Yes	N/A	Yes	
Montreal	Yes	No	No	Yes	
Toronto	Yes	Yes	N/A	Yes	
Peel Regional	Yes	Yes	N/A	Yes	Registration/ Education
Ottawa	Yes	Yes	N/A	No	Education
Ontario Provincial	Yes	Yes	N/A	Yes	
Regina	Yes	Yes	N/A	Yes	Registration Education/ Decals
Saskatoon	Yes	Yes	N/A	Yes	More publicity
Edmonton	Yes				
Calgary	Yes	Yes	N/A	Yes	
Vancouver	Yes*	No	No	Yes	
Victoria	Yes	No	Yes	Yes	Get ambulances involved

* decals as well

APPENDIX I

An Examination of Motor Vehicle Accidents in Alberta in 1982

by
Clare Dossetor

Motor vehicle fatalities in Alberta during the year 1982 were examined on the basis of age/sex, injury date and location, death date and location, as well as the stated cause of death. In total, there were 533 motor vehicle fatalities in the province - 162 of which occurred in South Rural Alberta, 191 in North Rural Alberta, 107 in Edmonton and 73 in Calgary.

To establish what number of these fatalities represented potential organ donors ideal and possible criteria were used to examine the age of the victim, the time elapsed between injury and death, the location of death and the stated cause of death. These criteria are:

1. Age of Deceased

   The ideal organ donor was considered to be 45 years of age or younger. All other victims who are over 45 and who have died from head injuries or from other injuries that do not rule out the possibility of organ donation will be considered possible but not ideal organ donors on the basis of age.

2. Time Elapsed Between Injury and Death

   In the vast majority of the fatalities investigated death was instantaneous. These cases were ruled out as not suitable for organ donation on the basis that circulation had ceased prior to the arrival of the police or the ambulance. Vital organ transplantation requires that circulation be maintained. Also excluded were those cases hospitalized for longer than a couple of weeks since these cases frequently die from subsequent infection. Those cases where death occurred en route to hospital were not excluded as they represent the people whose lives could have potentially been saved by a helicopter rescue service. Together with all cases where the patient was pronounced dead on arrival at the hospital, they will be considered as a separate group. The last category are those cases who reach a hospital and die within the first week of hospitalization. The latter group will be considered to be 'acceptable' on the basis of time.

3. Cause of Death

   The 'ideal' organ donor will be those who have died due to head injuries such as skull fractures, brain lacerations, cerebral edema, whereas all other non central nervous system related causes of death, as long as the patients are hospitalized for under a week and do not die from sepsis, will be considered "theoretically probable" organ donors.

The results of this study tabulated overleaf.

FATAL MOTOR VEHICLE ACCIDENTS, PROVINCE OF ALBERTA, 1982

TABLE I.1: OUTCOME AT THE SCENE OF THE ACCIDENT

	Calgary	Edmonton	South (Rural)	North (Rural)
Persons	73	98	162	185
% Died at scene of accident	32%	24%	87%	85%
% Reached Hospital	68%	76%	13%	15%

TABLE I.2: OUTCOME FOR THOSE REACHING HOSPITAL

Persons	50	74	21	28
Dead on arrival at hospital	5%	24%	28%	62%
Possible Donors	71% [1]	56% [2]	72% [3]	38% [4]
Died too late in hospital to be a donor	24%	20%	0%	0%

ACTUAL DONORS OF VITAL ORGANS

[1] 71% represents 35 patients of whom 5 **(14%)** became donors
[2] 56% represents 42 patients of whom 4 **(9.5%)** became donors
[3] **none** of these 15 patients became donors
[4] **none** of these 11 patients became donors

COMMENTS on these statistics:

1. The percentage of deaths at the scene of the accident is much higher in the rural areas, possibly because the response time is so much slower and the type of motor vehicle impact may be greater.

2. There is a much higher percentage of cases where the person injured in a motor vehicle accident is dead on arrival at the hospital in Edmonton than in Calgary. Could this be related to the differences in ambulance services?

3. Although the percentage utilisation of donors is highest in the two main hospitals, the overall donation rate for the cities is only **11.7%**.

4. This does not take into account other deaths not due to motor vehicle accidents.

APPENDIX J.1

Physician Utilization of Human Tissue for Medical Purposes in the Province of Alberta in 1983

by
Clare Dossetor

To establish the need for and supply of human tissue for medical purposes in Alberta, interviews were conducted with 19 medical specialists in Calgary and Edmonton and visits were made to four of the regional hospitals in rural Alberta. A report on each meeting was prepared and these reports include topics of discussion as well as suggestions or special comments on the subject. To simplify the research findings, each tissue has been dealt with separately to briefly address the questions of need and supply of the tissue as well as opinions on a Central Tissue Bank.

Bone

1. The Need for Banked Bone

Four orthopedic surgeons and two otolaryngologists were contacted in Calgary and Edmonton to discuss their need for and uses of banked bone. In the field of orthopedic surgery, banked bone is used most commonly for scoliosis surgery, spinal fusions and for treating non-unions of old fractures, though it is currently being used in joint transplants, in joint replacement revisions and for the en bloc excision of tumours. Seven joint transplants have been done to date (1983) at The Calgary General Hospital and twelve allografts with joint replacement as well as an en bloc excision for a tumour have been done at The University of Alberta Hospitals. The need for more bone to be made available for these last three procedures was expressed by three of the four orthopedic surgeons contacted and the expected future need for banked bone is higher still though no figures are available. Although the harvesting of intact bones for transplantation is currently being done only in Calgary, there are now plans to start harvesting joints in Edmonton and this would also increase the need for bone donations.

In the field of otolaryngology middle ear bones are being banked in both Calgary and Edmonton for transplantation purposes. The number of transplants done at the Royal Alexandra Hospital varies from one in several months to a couple each month (as is the case in Calgary), and human tissue is used whenever it is possible as it causes fewer complications than plastic ear bones. The incus is commonly used in the transplants though in the future it is expected that middle ear complexes (all three ossicles plus the ear drum) will be required for the treatment of radical mastoid cavities.

2. The Supply, Storage and Transportation of Bone

It is estimated that there are between 25 and 50 femoral heads kept in the operating room at the University of Alberta Hospitals at any one time (no figures are available for the Royal Alexandra Hospital) and there are between twelve and twenty joints and intact bones stored at the Calgary General Hospital. The supply of bone generally comes from surgical procedures when a hip fracture or joint replacement has necessitated the removal of bone,

though in the case of joint transplants the bone is obtained by bone donations through the H.O.P.E. program. In both cases bacteriological cultures are taken before and after the bone is stored in a freezer at -180°C and it is only in case of storing bone for transplantation that there is real concern about quality control. In all but one case the storage facility has been equipped with an alarm and temperature controls.

The present supply of banked bone often does not meet the current need and attempts have been made by three of the four specialists to obtain bone from elsewhere. Bone has been flown in to the University of Alberta Hospitals from the bone bank in Florida and on occasion a bottle of bone has been obtained from the Royal Alexandra Hospital when the supply runs low. Attempts have been made in Edmonton to obtain bone from Calgary and Vancouver and the specialist in Calgary expressed a desire to participate in a bone-sharing system set-up in the United States. It is estimated that between 50 and 100 joints and intact bones are required at the Calgary General Hospital (only 20 are currently stored) and in all cases it was believed that the present supply must be increased to meet the current, as well as the future, need for bone.

The supply of ear ossicles for transplantation comes from surgical procedures and cultures are taken before and after the bone is stored in a freezer in the bone bank. Although the present supply of ossicles usually meets the needs of the otolaryngologists in Calgary, it is estimated that in 75% of the transplants done in Edmonton, artificial prostheses are used due to the unavailability of human tissue. Cadavers were believed to be a possible new source of human tissue though they are not currently being used in either centre since there is no system set up for this type of donation. However, as the artifical bones function fairly well and are readily available at no great expense, there is no real concern over the shortage of human ear ossicle tissue.

3. Opinions on a Central Tissue Bank

Of the four orthopedic surgeons contacted, two were strongly in favour of a Central Tissue Bank, one was clearly opposed to the idea and the other believed that a tissue banking protocol together with several banking facilities were needed for the province. Although the response from one of the orthopedic surgeons was negative, all others interviewed expressed a need to have more bone made available to them and believed that a Tissue Bank could increase the availability of bone as well as guarantee good quality control.

Of the two otolaryngologists interviewed, one was opposed to a Central Tissue Bank storing ossicles for reasons of logistics and time, and while the other otolaryngologist did not believe that there was a serious need for a Tissue Bank he would take advantage of one if it was established. With regard to logistics and timing the need for ossicles is not often known until one is in the operating room, in which case bones must be on hand at the hospital. Should middle ear complexes be required in the future, however, it was believed that a Tissue Bank could help make these available as a cadaver source would be required and the need for the complex would be known in advance.

Bone Marrow

1. The Need for Bone Marrow

Of the two centres contacted, only the centre in Edmonton is currently using frozen bone marrow. The bone marrow is used for treatment of patients with chronic leukemias as well as those who have tumours of solid tissue origin (ovarian and testicular) and it is also being used for experimental and research purposes. To date 19 autogenous bone marrow transplants have been performed in Edmonton though there have not yet been any allogeneic transplants. Once the problem of immunological rejection is overcome, however, allogeneic bone marrow would not require freezing but would be infused directly. Frozen bone marrow is not being used in Calgary but two allogeneic transplants have been performed. In the opinion of both centres the expected future need for bone marrow is unclear and depends upon an overall improvement in its therapeutic benefits and results.

2. The Supply, Storage and Transportation of Bone Marrow

It is the patient's own bone marrow that is used for transplantation in Edmonton. The bone marrow of approximately 70 cancer patients is cryopreserved in liquid nitrogen and stored at the University of Alberta (one patient's bone marrow has been stored in this way for five years). The supply of bone marrow for the allogeneic transplants was not discussed though presumably it was obtained from a close relative and would not have required freezing or storage. In neither centre was there any transportation of bone marrow from other centres.

3. Opinions on a Central Tissue Bank to Store Bone Marrow

The specialist contacted in Edmonton believed that there was a need for a Central Tissue Bank though not necessarily to store bone marrow. However, should one be established, it would certainly be used. The specialist in Calgary, however, did not believe that a Tissue Bank located in Edmonton would be helpful to Calgary users of bone marrow for reasons of logistics and time and could not say whether or not it would be made use of.

Skin

1. The Need for Banked Skin

Of the two plastic surgeons contacted in Calgary and Edmonton, both felt that a skin bank is seriously needed for the management of serious burns. Human skin, however, is not currently being banked in either centre but it is estimated to be needed at least four times a year in Calgary and for approximately ten patients each year in Edmonton. Once banked skin is available, however, it would be used much more often and not only for these serious burn patients.

2. The Supply, Storage and Transportation of Skin

Skin is not currently being harvested and banked at either centre. In Calgary skin is taken for emergency use from fresh cadavers through donations from the next-of-kin. It is only on these occasions that there are any skin

donations at all as the facilities for skin storage do not exist at the hospital. In Edmonton porcine skin is used on serious burn victims and skin is also obtained on occasion from relatives of the patient. In Edmonton, however, there are no actual cadaver donations nor the facilities to store banked skin. There is no transportation of skin to either centres.

3. Opinions on a Central Tissue Bank for the Storage of Skin

In the opinion of the plastic surgeon at the Foothills Hospital, to have a skin bank located in any other institution would be impractical and to have it located in another city would make it practically useless for reasons of logistics and time. The plastic surgeon at the University of Alberta Hospital was very much in favour of a Central Tissue Bank and has long been awaiting its establishment. He would consider starting a skin bank at the University of Alberta Hospital, however, should the plans for a Tissue Bank be delayed any longer.

Brain

1. The Need for Human Brain Tissue

Only one neuropathologist in Calgary was interviewed to discuss the need for human brain donations. A supply of human brain tissue arises mainly from a need to study certain chronic neurological human diseases which have no animal counterparts (e.g., schizophrenia, Parkinson's Disease and Alzheimer's Disease). At the present time they have had 5 or 6 tissue donations of diseased brains in Calgary though there is a need for donations of some normal controls in order for research on these diseases to develop more fully. The frozen brains are currently being used for biochemical studies and Alzheimer DNA is now being looked at by the biochemistry department of the University of Calgary. The Calgary brain bank is still working mainly as a satellite of the Toronto based Brain Bank and although it is believed that research could be done in Alberta for conditions like schizophrenia, for rarer conditions (e.g., Huntington's Chorea) the expected number of brain donations in Alberta would be too few to make research feasible.

2. The Supply, Storage and Transportation of Brain Tissue

A system of procuring brain tissue has been set up at the Foothills Hospital which acts locally around Calgary and district together with the pathologists and with the nursing homes where many of the brain donations come from. The actual source of these brains is from donations made by people suffering from the above named neurological dioseases. The brains are harvested at the Foothills Hospital and then frozen and kept in a freezer in the Health Sciences Centre. The present means of freezing brain tissue, however, disrupts cell morphology and there is a need to be able to rapidly freeze these brains in liquid nitrogen in order to identify the cells involved in the release of specific neurotransmitters.

3. Opinions on a Central Tissue Bank for the Storage of Brains

The question of a Tissue Bank has already been considered by the lay organizations and both the Alzheimer Society and the Parkinson's Foundation are considering raising funds for a separate Brain Bank. In the opinion of the

neuropathologist interviewed, a Central Tissue Bank, if established, should be located in Calgary as it is only in Calgary that brains are currently being harvested.

Heart

1. Heart Transplantation in Alberta

Plans are now underway for starting a heart transplant team in Edmonton. At the present time there are three Canadian centres currently performing heart transplants though none are west of London, Ontario and there is now a need to establish a transplant centre for Western Canada. A specialist has arrived in Edmonton from Stanford where he has been involved in heart transplants for the past couple of years. It should be noted that Stanford is the busiest centre in the world for heart transplants and performs an average of one transplant each week.

It was believed that a Central Tissue Bank could function as a registry for the access to organs as there are problems in obtaining heart donations which a computerized donor bank could alleviate. As the bulk of hearts obtained for transplantation is not expected to come from local donations, it was thought that the donor-registry would have to be co-ordinated on a national basis to function properly.

Pancreas

1. Pancreatic Transplants in Alberta

Pancreatic transplants are not currently being performed on humans though there has been some success seen with dogs. At the moment there are approximately three or four cryopreserved human pancreas which have been obtained through donations and which are currently stored at the SMRI under the supervision of a cryobiologist there. The problems of autodigestion and immunological rejection, however, must be overcome before pancreatic transplants become clinically feasible.

Pancreatic islet cells are currently being injected into the splenic system of dogs where they will lodge and produce insulin. The cryobiologist in charge of this study is working in conjunction with a centre in St. Louis and has been quick-freezing islet cells and sending them to that centre for further research. It is not known when and if the injection of islet cells will become a clinical practice or when pancreatic transplants will be feasible but it is believed that a Central Tissue Bank could act as a storage facility for the islet cells as well as help increase the supply of pancreatic donations.

Bone and Skin Banking in the Regional Hospitals

1. The need for banked bone

Of the five regional hospitals contacted, only one centre was banking bone on a regular basis and none of the centres were banking skin. The reason for not banking bone was because the need for an ongoing bone bank

simply did not exist. Autogenous bone was being used in all centres for spinal fusions and for non-unions of old fractures, but this did not require banking.

For those cases who do require more bone than what is available from their own body stores (e.g., scoliosis patients), they are invariably sent to Edmonton or Calgary for treatment. The actual number of these patients never amounts to more than a couple each year and, as scoliosis surgery is not being performed in these hospitals, there was no perceived need to start banking bone for these patients. Although an ongoing bone bank did not exist in Lethbridge, banked bone had been flown down to the hospital from the Royal Alexandra Hospital in the past, though this has not been done at all in the last five years.

Of the centres visited, bone is only being banked in the Grande Prairie Hospital and is taken, whenever possible, from hip fractures and other accidents. It is estimated that usually twelve or so femoral heads and pieces of tibia are stored at any one time and that the 25-45 hip replacements done each year use up most of the bone on stock at the hospital. The bone is cultured before and after it is stored in a freezer and there is no concern about the quality control of banked bone. They are, however, awaiting a new freezer for the hospital and it is hoped that they will start performing knee replacements as well as start harvesting joints once the storage facilities are improved.

2. The Opinion on a Central Tissue Bank for the Storage of Bones

All of the regional centres visited were in favour of the idea of a Central Tissue Bank though it is only Grande Prairie that would make any real use of one as it often runs short of banked bone used. The specialist in Calgary, however, did not believe that any would benefit from having more bone available to the hospital. In the other hospitals, it is estimated that banked bone is not needed more than a couple of times each year though they would take advantage of a Tissue Bank in these instances if one was established.

3. The Need for a Skin Bank

None of the regional hospitals contacted are banking skin as the need does not exist for an ongoing skin bank. The main reason for banking skin would be for the management of severe burns but there is not enough of these cases in a year at any of the regional centres to make a skin bank feasible. It is estimated by all regional centres contacted that it is, at the most, only twice a year that burn patients are sent to Calgary or Edmonton and that as they are only secondary care hospitals, they do not anticipate having a burn unit in the future or a real need for banked skin. It should be noted, however, that human amnion is being stored on a regular basis in the Grande Prairie hospital and is commonly used on burns for its analgesic effects. Freeze-dried pig skin has also been flown in from Texas to the hospital in Lethbridge though it is not done on a regular basis.

APPENDIX J.2

SUMMARY OF TESTIMONY PRESENTED AT THE MEETING OF THE ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE ON TISSUE BANKING ON JULY 18, 1984 EDMONTON, ALBERTA

Dr. Jean-Michel Turc
Canadian Red Cross Blood Transfusion Service
Edmonton, Alberta

Dr. Turc provided the Task Force with information on the growing need for organs and tissues in transplantation by citing the following data provided by the 1982 Surgeon General's workshop: 5,000 patients were on the waiting list for livers; 6,800 patients were on the waiting list for kidneys and 5,300 transplants were done in 1982. There were 60,000 patients on dialysis, 20,000 of which were thought to be potential transplant recipients; 5,500 donors a year were needed to provide skin, just to support massive burn victims. There were 20,000 corneal transplants in 1982.

Dr. Turc also updated the Task Force on the work of the American Association of Tissue Banks study on the repertoire of all the Tissue Banks, legal and "illegal", operating in the United States. In the last three years five complete Tissue Banks have been established in the United States. He provided the Task Force with the following information:

- There is a need for a bone bank in Alberta. In Edmonton, there is an orthopaedic surgeon who imports tissue from Miami once a week or once every two weeks, six months ago nobody was importing tissue from Miami.

- There is a skin bank close to Atlanta, working for the whole United States, selling skin at a high price because there is such a real need. We should start to bank skin and bone within the next few years otherwise we will have to get bone and skin from the United States and the cost may be prohibitive. If you look at what has been happening in the United States in the last few years, one must conclude that there has been great waste.

- We have not been able to take full advantage of tissue and organ donors. A lot of cadavers used for kidney transplants have not been used for anything else. This is a shame when so any patients are waiting for transplants. It is possible for a Tissue Bank to deal with vital and non-vital organs if a medical professional is involved in the management of the cadaver and the collection of all of the organs.

- It's important to pool resources for public education and public relations in campaigns for procurement of all sorts of transplantable tissues and organs. This, also, is a principal role of the American Council on Transplantation; trying to keep all the organizations like the Kidney Foundation and the C.N.I.B. (and here in Alberta there are many, many more) co-ordinated and involved. Trying to put all these organizations under one umbrella is difficult.

- Administrative problems will have to be solved to make full use of donations.

- The nature of a tissue bank depends very much on what kind of tissue it deals with and how large it is. The smallest tissue bank is limited to one tissue. It serves the needs of one surgeon. At the other end of the scale is the component bank, organized to deal, effectively, with the entire scope of tissue banking, including the processing, freezing, freeze drying and storage of the tissue. There are now tissue banks with twenty thousand square feet or a few square feet, depending on what you are doing.

- We could easily adopt the routine practice guidelines and standards of the American Association of Tissue Banks for a tissue bank.

- The management and the organization of all procurements and collections of organs could be the duty of the tissue bank co-ordinators.

- One other Tissue Bank role beyond the administrative aspect, could be HLA typing. This could all be done at that central tissue bank, as well.

- We can put together a far better service if we do not have to rely on outdated information. New projects, new techniques, and new technology must all be developed by the research people associated with the tissue bank; the area is so new.

Dr. J.D.M. Alton
Edmonton, Alberta

Dr. Alton is a plastic surgeon who practises in Edmonton. He had the following comments:

- Any surgeon who obtains skin only for his own use does not need regulation as regards standards. On the other hand, when skin is obtained from another institution or when asked by another institution to provide the skin, you would have a degree of legal responsibility and standards would have to be established.

- In a centralized regulated organization, skin procurement would be done by a centralized unit which would be aware of the standards required, and adequately funded to obtain such standards; as distinct from each surgical unit "doing its own thing".

- Some of that skin is dissected here and some in Calgary. The treatment of burns now, in Alberta, is centralized in Calgary. Less significant burns are done in hospitals which look after burns. This is the way it should be. Edmonton looks after the Northern part of the Province.

- If we had a skin facility, or the tissue was available, we would use it three or four times as much as at present.

- There might be at least a hundred burns in Alberta, which would definitely benefit from a skin bank. At the present time, we have to hope to find a recent cadaver or bring a relative in to the hospital and take the skin graft from them. The best choice would probably be the mother but if the mother has four or five kids at home you don't do it. If you had a bank you

would use it much, much more and it would probably be a significant benefit to the patient and to the government, fiscally, as far as duration of hospitalization is concerned. Also instead of taking the mother under those circumstances there would be supplies available, you wouldn't have to cause that disturbance to the family, which is why we have done over half our treatments with pig skin. That is really just a temporary dressing and it is a compromise. There would be a saving of an admission to the hospital if a cadaver donation was used and you did not have to admit the mother to hospital for a skin grafting. The institution is also reducing the recipient's time in hospital; they can get a wound healed in ten days instead of a month. Two patients benefiting from a skin bank for $50,000 a year is the equivalent of two patients in a hospital for a month.

- Skin is a little scarce but there is no problem in harvesting skin. The director of the burn unit has to go and talk to the families. (Editorial note: families of the donors.)

- Cadaver skin will last for several weeks but the sooner you use it the longer it is going to last. The problem is that you don't know when you will have a burn patient and you don't know where you're going to get your cadaver skin.

- Based on information received from Vancouver, where they have a skin bank, if we have sufficient donors, we could look after the province of Alberta for $60,000.00. Its not an expensive proposition. What we really need is space and a technician and a suitable donor. The annual budget for skin banking is approximately $23,000 plus a technician - we would have to pay $50,000 to $60,000.

- If a skin bank were to be established any aspect to do with physicians would be under the power of the Council (of the College) and must come under the scrutiny of your committee or some other committee.

Dr. B. Boyd
Calgary, Alberta

Dr. Boyd suggested that if the Task Force reached the stage where they felt that the tissue bank was going to be a feasible activity, then it would be be worthwhile to have the College examine the question of standards.

- When we started in blood banking, there were very few, if any, standards; today they are rather extensive and we consider this absolutely essential. This progression is evident in the history of any type of procedure. In the early days of this century, with the first blood tranfusions, we had no standards. This was not liked, but it was condoned and accepted because of the situation at that time. They had gained one or two good successes and the losses were acceptable. Later, of course, standards were progressively developed and imposed.

- In 1984, and in the future we will not accept any procedure without adequate standards and we have excellent standards put out by the American Association of Blood Banks, and others.

- In this more sophisticated area and broaching the use of human material, it would be wise, to look at the standards and have them built in right from the very beginning.

- When you start out with small units and each person learns by their own efforts without help from any one else, there are many trials and many errors. Generally, you will find that centralization of the unit from the start permits some experience; one could consider decentralization when the knowledge and ability to handle some of these problems becomes simpler or more routine. If you can bring it to one area and put all your expertise in that area, you're going to end up with much better standards and much better facilities, even at the early stages.

- Bone banks have been available in Canada now, for over 25 years in many, many hospitals. Although very poorly run, in many cases, they were much better than having none. Very few people have full knowledge of what was required and what wasn't required, and there have been difficulties. We have now reached a stage where we should do a great deal more and do it in a much more efficient manner.

- We have taken skin for several patients in Calgary over the course of the last four or five years but the time has not always been suitable and sometimes they have had to delay the surgery until a donor became available. But remember when we talk about skin grafts this is only temporary skin -- eventually that has to be replaced by the patient's own skin.

- The Accreditation Committee of the College has a role in the preservation of the quality assurance in Alberta. This is a committee of the College, or the Council of College, and therefore our mandate is through the physician. If the facility we are talking about happens to be in a hospital or other non-physician operated unit, technically we have no control except over the physician who works in it. However, some ten years ago, the government of Alberta came to the College and asked us if we would take over accrediting of laboratories in this province. The College agreed and it is through that arrangement that we do accrediting of hospitals and other non-pathologist or non-physician operated organizations. We have been examining all private laboratories for some sixteen years now and we were the first organization in Canada to do that. We have been doing all hospitals in the province for just over ten years.

- For many years, this committee was the only one in Canada. All provinces except two now have them. The College of American Pathologists have been very kind to us in coming north of the border for very nominal fees to carry out inspections of hospitals and laboratories, until approximately a year ago, through the College accrediation program. But by the time the next accreditation comes out for the American Council, this will no longer be an accepted procedure in this province.

- Many things are performed in hospital labs which are not necessarily under the laboratory's direct control. Blood gases are often carried out in another section of the hospital under other persons. Yet it is directly under our control and we can pull a credit control of it.

- There are no standards as such for tissue banks at present. Eyes are generally

not sorted. They are taken fairly fresh and moved on or transported out of the province, if the surgeon who wants them is not available. But existing bone banks and bone marrow banks for example, with bacteriology and storage facilities do come under our control.

- Tissue banking standards could be supervised by the American Association of Tissue Banks as an interim procedure.

Dr. D. Modry
Edmonton, Alberta

Dr. Modry is a cardiovascular and thoracic surgeon who practises in Edmonton. He presented the following information:

- In the Northern California program the heart program team at Stanford is part of a bigger oganization which procures all tissues. The background with heart, heart/lung is that there are currently no feasible means for preserving the heart or the heart/lung for longer than about 5 to 6 hours on a routine, reliable basis.

- With regard to collaboration, with the Northern California tissue bank, and R.O.C.A. which is a regional organ procurement agency in Southern California, Stanford has always had the policy of letting at least two procurement centres know their recipient's needs. For example, there might be 12 - 15 heart and 8 or 10 heart/lung candidates waiting. In Southern California and Northern California serum would be available from each of these recipient candidates. (Ed. for tissue crossmatching). In fact, there would often be calls to Stanford from centres other than those two organ procurement agencies, though the latter provided about 75% of the organs. It was really an excellent system.

- One of the problems being faced in California right now is that San Francisco Medical Centre, U.C.L.A. and also San Diego are now starting to do transplants. This has put further strain on Stanford in obtaining organs from Northern and Southern California procurement agencies. This has generated an immediate need for more donors, with the background belief being that only 10-15% potential donors are actually being used at this time.

- There needs to be more public and physician education as to our patient's needs.

- The procurement of organs is different from the storage or organs but that doesn't mean administratively they couldn't function through the same centre.

- At Stanford, all tissue procurement is co-ordinated by the Northern/Southern Procurement agencies, so that all of the appropriate physicians are notified that there is a donor available and as soon as the vital organs are harvested and the skin, cornea and bone, ossicles or whatever are removed.

- Now, what has happened locally at Stanford is that when a donor becomes available directly to Stanford and does not go through one of the procurement agencies is the Stanford transplant co-ordinator then contacts the appropriate cornea and skin people. Prior to one year ago, the transplant chief

co-ordinated all the transplants and was the transplant co-ordinator in Stanford, surprising as that may seem. There have been a number of meetings, very much like this one, to try to generate better co-operation in organ sharing and better procurement of donors.

- There is no doubt if Alberta was established as a centre for transplantation then a cryobiology unit, or a tissue banking centre, would go a long way in helping to reinforce that concept.

- The issue of need is addressed in two areas. One is the need for heart, heart/lung transplantation. We are in the process of accumulating data on the number of patients that could conceivably be benefited by heart or heart/lung transplantation. There are a large number of patients in the area that could benefit. There is no doubt about need. Cost prior to death in patients who are not transplanted in fact exceeds the cost of transplanting the patient.

- A central facility would be a benefit for heart, heart/lung transplantation. The research and development that goes into the central organization may at some point in the future provide a system where heart and heart/lung can be preserved for a long period of time. There is also an advantage to centralizing in terms of education and media information to the public and perhaps to other physicians as to what the needs are.

- It has always been the philosophy of heart transplant surgeons that it is cost-effective. There is data from Stanford, for example, that shows in excess of 90% of the patients who lived beyond three months following the transplant have been fully rehabilitated. Some don't return to work because they decide to retire but they could if they wanted to.

Dr. Modry spoke of the need for financing procurement and its cost effectiveness when compared to other types of treatment.

- If a patient had carcinoma of the lung, esophagus, pancreas, we would spend a great deal of money in treating that patient with the end result, almost universally, being that the patient dies of the disease. The cost of looking after those patients again exceeds the cost of transplantation for heart or heart/lung. The one year survival rate with lung, esophagus or pancreatic malignancy is less than 10%. But we are talking about an 82% one year survival rate with heart transplantation. So there are different ways of looking at it from a cost effective point of view.

- The Stanford program does not pay sufficient fees for harvesting. Heart/lung donors are always in the institution at which the transplant is performed. With heart donors, the hearts are always procured by a surgeon who is a member of the transplant team and there is no extra cost to anybody. The surgeon does not get paid for that. In fact N.I.H., until recently, funded all costs of the transplant program and, as you are probably aware, Blue Cross/Blue Shield and even Medicare are starting to fund the transplantation in California.

Dr. L. E. McGann
The University of Alberta
Edmonton, Alberta

Dr. McGann is a cryobiologist in the Department of Pathology at the University of Alberta. He presented the following information:

- At the moment the state of the art of cryobiology is that we can freeze and preserve viability of small bits of tissue, like embryos,

- We are also able to transplant thawed islets of Langerhans (which secrete insulin and are defective in diabetics). These are, again, quite small bits of tissue which are isolated (so it is not the whole pancreas actually that we are preserving) before freezing in liquid nitrogen. When we consider vital organs, which are large and complex, a lot of experimentation is being carried out trying to develop appropriate techniques. There are no fundamental barriers to developing techniques for eventual preservation of vital organs. If and when vital organ preservation becomes a reality, the need for organ banking will be self-evident.

- In terms of preservation of viability of cells and tissue, the requirements are very exact for storage and for freezing. This is where a centralized facility will offer a wider range of medical applications than currently exist right now. If it existed, more people would actually use it, because the tissues would be available, and secondly having it done under controls, personal liability would no longer concern physicians.

- Many banks are being operated under the conditions which were relevant ten years ago, when these people learned how to do it, and they are maintained that way. A good example actually is what happened with those embryos that were frozen in Australia under conditions which were current in 1981. Fetal cryobiology is changing, as you are probably aware. More and more tissues and bigger bits of tissues are being frozen and thawed successfully, and then used clinically. Procedures have to be updated because they make a big difference in terms of the utility and viability of the tissues.

- With the cartilage and bone, like many other tissues, the more you understand about how to make it survive better in storage, the more exacting the demands become. Freezing conditions and storage conditions are critical. In fact, even the salvage procedure is becoming critical in cartilage as well.

- Freezing blood cells (single cells isolated in suspension) has been successful since about 1950. It has been relatively easy to freeze and also to maintain high viability for long periods afterwards.

- When freezing bone the viability of the material is not important, only its structural aspect. It is an attempt to prevent contamination with bacteria rather than preserving the material. But for preservation or viability, one requires an understanding of the particular cells that make up the material - how they are structured, what their requirements are.

- There has been a major re-examination of techniques needed to store corneas.

Corneas have been stored (frozen) since about 1953. The techniques that were used up till 1980 were largely ones that were evolved in 1953 in England. The techniques that have been used for cornea preservation are being reassessed, and limitations in previous techniques are evident.

APPENDIX K.1

ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE

QUESTIONNAIRE ON

BARRIERS TO TRANSPLANTATION WITHIN THE MEDICAL PROFESSION

1. *College of Physicians and Surgeons and Alberta Medical Association*

   a. What is the position of your organization on the subject of vital organ transplantation? Are all organ transplant procedures viable interventions or are some experimental?

   b. To what extent is organ procurement a physician's responsibility?

   c. Does a physician have an ethical obligation to encourage the donation of vital organs for the purpose of transplantation?

   d. Is the lack of a legislated definition of brain death a barrier to participation in organ procurement?

   e. Should a non-transplant physician be compensated for counselling the donor's family on organ donation? If so, should compensation depend on the physician's success in obtaining the donor family's consent?

   f. Are you aware of any specific problems non-transplant physicians face which prevent them from referring organ donors to transplant teams, and have you any suggestions as to how those problems could be alleviated?

   g. Under what circumstances would a physician be compromised ethically by accepting or counselling an organ donation?

   h. Would physicians be assisted in organ procurement activities if legislation were passed making consent to donations presumed in the absence of known objection? The approach to the donor's family would then be along the lines of "Did the deceased have any objection to organ donation of which you are aware?" rather than Would you be willing to consent to donating the kidneys, corneas, etc., of the deceased?"

   i. Are you or your members generally familiar with the H.O.P.E. program currently based at the Foothills and the University of Alberta Hospitals?

2. *Alberta Association of Registered Nurses*

   a. What is the position of the A.A.R.N. on the general subject of organ transplantation?

   b. Does a nurse have an ethical obligation to encourage organ procurement?

   c. If nurses have an ethical obligation in the organ transplantation process, whose responsibility is it to approach the donor family?

   d. Are you aware of any specific problems facing nurses which prevent

them from referring organ donors to transplant teams, and have you any suggestions as to how those problems could be alleviated?

e. Would organ procurement activities be assisted if legislation were passed making consent to donations presumed in the absence of known objections?

f. Are your members generally familiar with the H.O.P.E. program currently based at the Foothills and the University of Alberta Hospitals?

3. *Critical Care Physicians, Emergency Room Physicians, Neurosurgeons*

a. What problems do you and your colleagues face when attempting to participate in organ procurement? Do any of these relate to:

1) concerns over organ transplantation as a form of treatment;
2) lack of time to deal with obtaining the consent of the donor's family and/or lack of appropriate compensation for that time which is spent;
3) apprehension as to potential legal liability;
4) lack of information as to what proceedings must be carried out, both medically and administratively;
5) general distaste for organ donation process;
6) ethical concerns not previously referred to.

b. Do you have any suggestions as to how those problems could be alleviated?

c. In what way would you and your colleagues be assisted in organ procurement by a legislated definition of death (which would include brain-death) and do present brain death protocols in the hospital where you practice affect organ donation?

d. Would you and your colleagues be assisted in organ procurement by legislation which would provide for presumed consent to organ donation in the absence of express refusal? If not, why not?

e. Are physicians being made aware of organ procurement during their training? If not, at what point in the course of medical education could such information be put forward?

f. Do you have any objections to:

1) compensating organ donors for inter-vivos donation?
2) compensating the donor's estate and/or his family in the case of post mortem donation situations (for example, payment of burial costs as is done for cadavers under the Universities Act)?

4. *ICU Nurses, Neurosurgical ICU Nurses and Emergency Room Nurses*

a. Do you and your colleagues face any problems when attempting to participate in organ procurement? Do any of these relate to:

1) poor support by practitioners of organ transplantation as a

treatment?
2) lack of time to obtain the consent of the donor's family?
3) apprehension as to potential legal liability?
4) lack of information on medical and administrative procedures to be observed during organ donations?
5) general distaste for organ donation process?
6) ethical concerns not previously articulated?

b. Do you have any suggestions as to how those problems could be alleviated?

c. Are nurses being made aware of organ procurement during their training? If not, at what stage could such information be put forward?

5. *Medical Directors*

a. Does your hospital have a policy for routine salvage of cadaver organs? If not, would you be willing to recommend one? What sort of reception would you expect to mandatory procedures for:

1) emergency rooms
2) intensive care units.

b. What sort of brain-death protocol does your hospital employ? Would you be willing to revise that protocol if it were shown to be a barrier to organ transplantation?

c. If it were hypothetically possible to retrieve vital organs from every potential donor being treated in your hospital and arrange for their transplantation either in your hospital or elsewhere, what medical programs and facilities would require expansion (based, hypothetically, on a 500% increase in retrieval and transplantation)?

APPENDIX K.2 SUMMARY OF TESTIMONY PRESENTED AT THE MEETING OF THE ALBERTA HUMAN TISSUE PROCUREMENT TASK FORCE ON BARRIERS TO ORGAN PROCUREMENT EDMONTON, ALBERTA, NOVEMBER 21, 1984

Dr. Robert F. Clark
Executive Director, Alberta Medical Association
Edmonton, Alberta

The AMA has promoted transplantation for a number of years and was instrumental in the inclusion of the Universal Donor Card on the Alberta Operator's licence. Dr. Clarke spoke of the efficacy, appropriateness and necessity for organ transplants as an issue to be resolved by scientists and clinicians. He made the following statements:

- The AMA is of the view that the responsibility for organ procurement is a shared one between the public, the medical profession and the government, that the physician should play a major role in the system overall and should encourage organ donation and procurement on an individual case basis but that the physician can only play his role in an environment in tune to this activity. The aim of their program is to move government, public and the profession towards this awareness, in order to see an expansion in human organ availability.

- Dr. Clark outlined the CMA Code of Ethics on transplantation which are permissive, and recognize that it is ethical for the physician to preserve cellular life for organ donation. They have been adopted by the AMA and the College of Physicians and Surgeons. The area of organ transplantation is covered in the Code of Ethics in Sections 20-23 in the Responsibilities to the Patient.

  An Ethical Physician:
  20 may, when death of the brain has occurred, support cellular life in the body when some parts of the body might be used to prolong or improve the health of others;
  21 will recognize his responsibility to a donor of organs to be transplanted and will give the donor or his relatives full disclosure of his intention and the purpose of the procedure; in the case of a living donor, he will also explain the risks of the procedure;
  22 will refrain from determining the time of death of the donor patient when he will be a participant in the performance of the transplant procedure or when his association with any proposed recipient might influence his judgement;
  23 who determined the time of death of the donor may, subsequent to transplant procedure, treat the recipient.

- Since physicians are perceived as the primary persons responsible for the patient, they should be the leader in approaching the family in respect to obtaining an organ. The physician may delegate the responsibility to a transplant procurement officer but the ultimate responsibility remains with that physician.

- A definition of brain death is probably not necessary for the well informed physician like the neurosurgeon, but it could be a form of reassurance for the physician who has limited knowledge and is only occasionally involved in the

diagnosis. We have provided a definition of brain death to our members (of the Alberta Medical Association) for use as a guide but, when we did so, we were told by the Chief Medical Examiner that the only legal "definition" of death is the traditional one.

- A legislated definition of brain death would produce a more positive attitude toward organ procurement. If the average physician had that available, he might feel more comfortable about making the decision that a patient was brain dead.

Dr. Perry

Dr. Perry is personally of the view that doctors have an obligation or responsibility to facilitate organ transplantation and that it is the duty of the physician rather than any of the other health care workers to facilitate transplantation. He outlined the difficulties in emergency room patient care. On the termination of patient care and discussions regarding donation, Dr. Perry expressed concern about anyone other than the responsible physician initiating a discussion on organ transplantation with the patient's family.

Prior to appearing before the Task Force Dr. Perry had never heard the word H.O.P.E., did not know where to contact H.O.P.E. and had never had any contact or discussion with the H.O.P.E. co-ordinators. This view was almost universal among the collegues at his hospital. Dr. Perry made the following observations:

- The last time corneas were requested in my emergency department, a consent form was not available.

- There are no protocols on maintenance of kidneys to the maximum function.

- There is rarely any feedback on what happens to the organs, whether they were used, if it was successful or whatever. And these are factors which influence the attitude of acquisition for next time.

- It is inappropriate for some one involved in peripheral care of the patient such as a clergyman to approach the family, initially. It could raise serious legal implications as well as moral and ethical problems.

- The responsible physician should make initial contact. He may then delegate other members of the team or a specialist in that area to follow through. It is the physician's responsibility to counsel the patient's family regarding donation in order to preserve the continuity of patient care.

- We are discouraged from admitting someone to hospital who in fact is brain dead. The nurses get upset, the administration gets upset, and the ICU director gets upset.

- Emergency physicians have problems with the availability of donor cards. Even if they are available and if we then approach the wife and she says, "No, under no circumstances, even though he signed that card", physicians would be reluctant to pursue the matter.

- My colleagues have compassion for the widow or for the family. They do not feel that they want to go against them on this issue, whether it was legally right or not.

- A physician, should not protest the wishes of the widow of a potential vital organ donor. A thing may be legally right without being morally and ethically right.

He made the following recommendations:

- There should be a central telephone number.

- There should be a plasticised manual for organ donation procedures in the emergency department, and other areas, which is updated as required.

Dr. Boyar, Calgary

Dr. Boyar is an emergency room physician who practises in Calgary. His group was also unfamiliar with the H.O.P.E. program. In an informal survey of his group no one knew how to get hold of H.O.P.E. or what the central number was. Dr. Boyar provided background information on the situation in the emergency room with respect to organ procurement.

- In the emergency room when a possible donor is being examined the only person that can make the whole exercise a success is the emergency room physician since he is the only one who will have the awareness to continue the proper treatment such as the perfusion of organs.

- The physician should be a leader. He is the one who can determine whether or not the patient is going to survive.

- The physician can initiate the process but the development of the professional procurement officer is necessary because physicians don't have time to pursue the procurement of tissue.

- This diagnosis can readily be made by a very well-trained physician who knows all the clinical parameters of death; but there is still the magnitude of the decision and the fact that life is very special and this person is being declared dead. Many physicians also feel the need to have the backup of defined criteria, as well.

- A problem with the donor card is its availability. Often it is in the policeman's pocket at the scene or in the ambulance driver's pocket, because he's looking for the Blue Cross number, or it is at the front desk because the receptionist has to make up the chart, or it has already been filed in safe keeping. Very rarely do we ever see a wallet with any kind of cards that can identify. This is a big problem. That is why have a lot of trouble with this whole concept of a card. And the Alberta Health Care card is no more available than the driver's licence card.

- One of the things that people do not like to deal with is their own

mortality. One of the things which impedes signing the card is that one is being asked to acknowledge one's own mortality. For that reason we will never get wide card usage.

Recommendations:

- The public needs to be educated, in respect to this whole area in the broader sense as well as to particulars.

Ms. Betty Tomte, R.N.
Assistant Registrar, A.A.R.N.
Edmonton, Alberta

Ms. Tomte presented the position of the AARN.

- The AARN has not developed a formal position on organ transplantation.

- There is a general acceptance by members of the Association of transplantation being a treatment and therapeutic benefit.

- The AARN is currently examining the issue of whether a nurse has an ethical obligation to participate in organ procurement. Nurses do participate in the process of encouraging organ donations, but in terms of the individual member and the ethics at this point, the AARN does not have a position.

- The responsibility to approach the donor's family is a shared responsibility. It can be the physician, it can be the nurse, it can be any one of a number of people involved in that situation, when someone is dead or brain dead. It is not necessarily the physician's, the nurses' or the clergy's responsibility. The responsibility needs to be delegated to someone and that someone should be the most appropriately trained individual with communication skills. In certain situations, it may be appropriate to remove that burden and delegate it to a specific category of health care worker. Who the most appropriate people are would have to be determined within the institution.

- The AARN has met with the nurses involved with the H.O.P.E. program and supports their work. The transplant co-ordinators who are located in the two main centres are expected to reach all of the physicians and nurses in Alberta. This is unrealistic because their resources are limited. The advantage of someone outside the actual care team in approaching the donor family is the follow-up that the family may get after the organs have been donated. Without someone charged with that responsibility, follow-up may never occur. In centres without a H.O.P.E. co-ordinator, the transplant co-ordinator could be a member of the nursing staff who would be trained with the necessary skills for that agency.

Dr. Peter B. Allen

Dr. Allen is a neurosurgeon who practises in Edmonton. He spoke of the difficulty that physicians may have in approaching a family with the news that the

patient is about to die and then requesting a donation. He made the following comments to the Task Force on brain death:

- The most important criteria in brain death is the historical aspects of how the patient got into the state that he is in. Occasionally, we find ourselves in a situation where we are presented with a patient who is not responding and not doing a lot of the things that are normally associated with normal life, but we really do not have a good idea of what has happened. This makes it much more difficult. Thus one criterion is knowledge of the prior sequence of events. We have a number of other criteria: the inability to maintain respiration on one's own; the inability to maintain adequate cardio-vascular perfusion; the inability or ability to respond to external stimuli; the presence, perhaps, of brain stem stimulation. However, as we teach in medical school, no single examination is valid unless you compare it with those previously obtained, in that patient, and in conjunction with the other criteria. Thus, before we try to establish gross impaired cerebral function or total absence of brain function, we go back and do it again at some later times, perhaps an hour or longer, and show that they have not changed.

- There are various lists of the criteria for brain death. Some also add electrical stimulation to them, depending on whether he is using Canadian or American criteria.

He also commented on transplantation generally:

- Our first area of concern is the education of the public and the medical profession as a whole. The public to a degree was much easier to educate and make aware of the problems than many of our medical colleagues.

- The physician has to be the one who makes initial contact as indicated in our Code of Ethics.

- The physician who discusses donation with the family must not, or certainly should not, have any interest in the transplant after that point.

- It is an extremely difficult and unpleasant experience, both for medical staff and nursing staff to request a donation.

- Initially we encountered great difficulty with our staff trying to get them to accept donation. As time has gone on, this has become progressively easier as the direct benefits of the renal transplant have been made apparent to them.

- Dr. Allen also expressed concern about the universality of obtaining donors and organs throughout the province, particularly the availability of appropriate facilities to assess the death of the individual.

Dr. Cochrane

Dr. Cochrane is a neurosurgeon who practises in Calgary. He has seen the transplant program evolve over the past seven years in southern Alberta. He provided the Task Force with information on why the donor patient is irreversible from the neurological perspective (why he's brain dead) and responsibility of the

neurosurgeon in regard to organ donation. He also discussed the difficulties that families have when asked for a decision on donation of organs. Dr. Cochrane spoke of the frustration he had experienced in the neurosurgical units four or five years ago establishing organ donation. At that time physicians were reluctant to get involved in with potential donors because it was difficult and there was no feedback. It was Dr. Cochrane's view that his obligation is to the patient and it was his responsibility to establish a valid answer to the controversial question imposed on the family.

- Physicians in Southern Alberta will, in fact, refer patients over the telephone conversation in this way: "This patient is not well neurologically, it's appropriate to present him as a donor". That patient will be sent as a living patient to have the diagnosis of brain death established at our facility.

- The criteria for organ donation could be adequately taught in the course of medical education, both at the medical school level and that of the intern in the emergency room.

- The need for education really lies with the physician-resident interaction because many residents are caring for these individuals.

- Education is required more in the general public than within the medical profession.

- Physicians should handle the physician-physician education.

- What physicians cannot handle is a family that has not been prepared for this kind of questioning. That is a hard thing to deal with and it is time-consuming because there are multiple discussions, all of which seem to be at least an hour. Then the family must have time to consider it.

- In response to the question whether physicians had an ethical obligation to encourage organ donation, it was Dr. Cochrane's view that physicians have an obligation to ask the question.

Ms. M. Smith

Ms. Smith is an ICU nurse. She is of the opinion that if there was a H.O.P.E. co-ordinator in the referral hospitals fewer patients would be lost. She made the following points to the Task Force:

- We get two types of patients declared as transplant donor candidates. Some patients come as referrals, in which case the H.O.P.E. co-ordinator has usually done all the preliminary work with families and quite often they do not even come to the unit. The second case is when the patient is already in the unit and his diagnosis and prognosis has to be established, there. Once that is determined by the director of the unit in neurology, the H.O.P.E. co-ordinator is invaluable. She organizes tissue typing, OR time and she is wonderful with the family.

- Most of our candidates, transferred from other hospitals, are being admitted to our unit after death has been confirmed somewhere else - Children's, General.

They come in as such, already set down as brain dead, often completely missing the emergency department, coming in directly to the unit.

- As nurses our role in the second situation is very important because the H.O.P.E. has so many demands.

- The initial concept has to come from the doctor making the decision of brain death, and then followed very closely by the nurses involved with that patient's "life support".

- More public education is required in Alberta. We'd get a lot more patient donations. When working with brain dead candidates, it is vital that the physician makes the decision and works with the family, with the nurse present. If the family is aware of the situation and is approached about donation of organs for transplantation, it becomes a very simple matter, The physician can step out easily; the nurse is there and she then works very closely with the H.O.P.E. co-ordinator, the latter being invaluable in organizing all those things because the nurse is not always aware of the proper procedure or the key contact persons.

- There is uncertainty regarding the nurses' position on procurement.

- Often the best encouragement for the nurses is the follow up that they see. The follow up done by the H.O.P.E. co-ordinator is phenomenal. We have sometimes seen these families and patients for an extended period of time and we become very involved with their psychological support. Just knowing that your work with the dying patient and the family has been rewarding to somebody else, who has benefited from it, is something that you have to experience. That's the one thing that nurses feel very strongly about, it's a very key part of their role.

- One of the situations that is confusing is the issue of the driver's licence card. In a hospital when a trauma patient comes in, often those kinds of things are not looked for when you gather up the person's valuables. Medicine is oriented to save people's lives and we do not always think about death.

- There is a lot of misinformation among nurses about the legality of organ donation procedures.

- Nurses should be educated regarding organ donation in their training. It is vital to do it at a training level and again later. Each institute has to have a policy, and each must undertake that responsibility.

Dr. Sandham
Director, I.C.U.
Calgary General Hospital

Dr. Sandham provided the Task Force with information on the type of patient he treats in the ICU. Only the patients that are resuscitated but are brain dead when they reach ICU are suitable for organ donation and this is not a large group. There may be a problem with gaining consent to organ donation. He made the following points to the Task Force:

- Professional education is needed.

- Awareness is more important than specific protocols.

- The urgency of this decision making may perhaps have been over-stressed. For vital organs, such as kidney, usually the time sequence is such that the patient does not have to be an hour in emergency. Usually there is time for the necessary consultation with a neurosurgeon or neurologist before those organs are harvested.

- With respect to non-vital organs, such as corneas, the process of obtaining consent for non-vital organs is much simpler.

- It is a difficult thing, emotionally to approach the family and there is no consensus on this with the staff. A lot of the support which the family gets comes from the nursing staff, so it is important that they be involved in the discussion from the outset.

- On the other hand, ultimately, the physician has to accept responsibility for the consequences of what happens. Whether the family says yes or no, the physician is still left carrying the ball. (It is for this reason the Dr. Sandham is uncomfortable with people taking initiatives with patients unless discussion and consensus have been achieved beforehand.)

- There are circumstances where it may not be appropriate to approach the family, or where they should be approached in a certain way. It is for these reasons that there are no initiatives by the ICU staff until we have had discussion and they have my agreement.

Recommendation:

- It would probably assist this problem of identifying donors if we had an agreed set of criteria of brain death.

Ms. Lynn Fester
Administrative Officer to Vice-President (Medical)
University of Alberta Hospitals
Edmonton, Alberta

- There is no overall hospital policy on admitting brain dead bodies. There has been some professional agreement between the medical director of the ICU and others. From the point of view of economics, it would seem that here there is need for a written policy.

- It might be helpful to have a physician from the medical accounting department on this whole issue of concerns about transplantation. Hospital administration would be supportive in working at program changes and creating new policies and procedures. In the Edmonton area, there is a forum for this kind of thing: for example, consent forms that are universal; what happens in the emergency rooms from the point of view of the hospital transfers; the care of brain-dead donors, their transfer and admission.

Dr. Lorne A. Klippert
Vice-President Medical Services
Foothills Hospital
Calgary, Alberta

- The Foothills Hospital does not have a policy that a brain dead patient cannot be admitted.

- As a receiving hospital, we do not provide a barrier to these admissions, be they patients or bodies, nor could we reasonably be expected to do so and run a central transplant program.

- The way to expand our transplantation program is to increase the already good work being done by the H.O.P.E. program.

- With the more global issue of financing though, it is not quite that easy. A doubling of the program might imply a substantial increase in load on a number of individual professionals and nursing staff, on the ICUs and this implies increase in staff as well as staffing in other related ares, such as our operating rooms, with substantial dollars out of our drug budget.

- Doubling the size of the H.O.P.E. budget, though it doubles the success of our transplant program, will certainly cost more in other area in a hospital like Foothills. To the extent that we cannot expand our services to take those additional patients, or expand our budget to effect additional programs, with increased cost, will mean more of the sort of rationing out that hospitals take on as one of their duties.

APPENDIX L.1

LEGAL ASPECTS OF THE TRANSPORTATION OF VITAL ORGAN DONORS IN ALBERTA

Janice E. Trylinksi, M.Sc., LL.B.

In the very near future it may be necessary to transfer a person identified as a potential donor from hospital to hospital within Alberta, or from a hospital outside Alberta to one within Alberta, or from within Alberta to outside Alberta. The person being transferred may have been diagnosed as brain dead or may be suspected of being brain dead before transport. In one centre in Alberta, by convention, the time of death is stated as the time when mechanized support is discontinued.

The Law in Alberta Regulating the Removal and Transportation of Bodies

There is no law in Alberta which restricts the transportation of brain dead donors maintained on organ support systems. However, there are laws regulating the removal and transportation of bodies or dead bodies. They are:

Section 25(1) of the Operation of Approved Hospitals Regulations, A.R. 146/71 as amended to A.R. 226/82:

"25(1) No body shall be removed from any hospital until
(a) it has been examined by a physician and he has made a notation on the record of the time of death and has signed the notation; and
(b) until proper authority has been received by the hospital administration for such removal."

Sections 15 and 16(1) of the Fatality Inquiries Act, R.S.A. 1980, c. F-6:

"15 When a body is brought into Alberta for ultimate disposal, a funeral director, undertaker, embalmer, mortuary attendant or other person who intends to dispose of the body shall, before disposing of the body, notify a medical examiner who shall
(a) inspect the medical certificate of death or other documents which accompany the body,
(b) cause to be made such investigation as may be necessary to establish or confirm the cause of death, and
(c) countersign the burial permit before disposal of the body.

16(1) No person shall
(a) cremate a body, or
(b) ship or take a body from a place in Alberta to a place outside of Alberta, until a medical examiner issues a certificate stating that he has caused the body to be inspected and has examined the medical certificate of death."

Section 14(3)(a) of the Vital Statistics Act, R.S.A. 1980 c. V-4:

"The personal particulars requested pursuant to subsection (2) shall be provided before (a) the disposal or shipment of the body of a deceased person..."

(Section 14(2) refers to the personal particulars of the deceased person which are to be completed by a priority list of relatives and persons who knew the deceased.)

Section 18(5) of the Vital Statistics Act, R.S.A. 1980 c. V-4 :

"18(5) When a death occurs outside Alberta and the burial or other disposition of the body is to take place in Alberta, a burial permit or any other document that is prescribed under the law of Alberta or country in which death occurs, signed by the district registrar or other proper officer and countersigned by a medical examiner, is sufficient authority for the burial or other disposition of the body."

There are also regulations regarding the transport of bodies affected by specific communicable diseases, viz. Provincial Board of Health Regulations Respecting Preparation and Transportation of Dead Bodies, Funerals, Interment and Disinterment, A.R. 227/73, as amended by A.R. 336/75.

The Law on "Brain Death" in Canada

Before proceeding with a discussion and analysis of the transport of a brain dead donor in Alberta it is of interest to review the laws in Canada regarding brain death.

Manitoba is the only province in Canada which has a legislated definition of brain death. Manitoba is also noteable in having the only judicial recognition of the concept of brain death. Since this is the only case in Canada it will be examined in detail.

In Regina v. Kitching and Adams [1976] 6 W.W.R. 697 (Manitoba Court of Appeal) the appellants Kitching and Adams were charged with manslaughter by causing the death of D. G. Junor by an unlawful act. At trial they were convicted by judge and jury and were sentenced to four and five years respectively in the penetentiary. The appellants appealed both conviction and sentence.

Junor had been found in a highly intoxicated condition in a bar in Winnipeg and had been taken outside by the accused and dropped onto the concrete sidewalk. An ambulance was called. On arrival, the ambulance attendant examined Junor and could not detect any sign of life and attempted to resuscitate Junor. Junor was taken to the Health Sciences Centre and after seven minutes of continued resuscitative procedures, a pulse was obtained and respiration restored. This was about 1 a.m. on July 24, 1975. Junor was later attached to a respirator. By 7 a.m. on July 24, Junor was unresponsive neurologically. A neurologist was called in in the afternoon of July 24th and at 11:00 on July 25, 1975. On the second examination the neurologist found that Junor was unable to breathe on his own, that there was no evience of response to external painful stimuli and that there were no reflexes. The neurologist could detect no brain stem function. All of this indicated brain death and no chance of any recovery.

In the early afternoon of July 25, 1975 Junor suffered a cardiac arrst which would have normally ended his life, his bodily functions were maintained until his kidneys were removed for transplant purposes. The purpose of maintaining Junor's bodily functions was to preserve his organs, not his life. After the kidneys were removed for transplant purposes, the artificial respirator was turned off and the formal death certificate was completed.

Counsel for the accused argued that their clients should not be convicted of manslaughter because there was a possibility on the evidence that Mr. Junor was not killed by the acts of the accused but as a result of the acts of doctors who removed the deceased's kidneys and shut off a life-suppoting ventilator.

On appeal, the Court of Appeal of Manitoba upheld the convictions but reduced the sentences. In reviewing the case and the evidence on the cause of death, the Court of Appeal were of the opinion that the question of causation was plainly put to the jury and that the accused did cause the death.

In any event, in reviewing the case Mr. J. O'Sullivan pointed out that it is not necessary to prove that a criminal is the sole cause of his crime and that there may be two or more independent operative causes of death. He stated at page 715 of the case:

> "Without in this case criticizing the doctors of Health Sciences Centre or suggesting that they were guilty of any improper conduct, I am of the opinion that their conduct was irrelevant to the questions before the jury. Even if it could be shown that the actions of the doctors constituted an operative cause of Mr. Junor's death — and I emphasize that I do not suggest that the evidence would support such a conclusion — still that would not exonerate the accused unless the evidence left a reasonable doubt that the accused's actions also constituted an operative cause of the deceased's death.
>
> On that question, the evidence was overwhelming. Whether or not the kidneys have been removed, the deceased could not have lasted more than a short period of time even with artificial assistance.
>
> The jury had to decide not whether the doctors were ethical or not but simply, did the accused cause the death of the deceased by unlawful means? The question of causation was put to the jury plainly; they decided that the accused did cause the death. The evidence was overwhelmingly in favour of their verdict."

Mr. Justice O'Sullivan also discussed the issue of the definition of death and since it is the only recent judicial pronouncment on the definition of death and since it grapples with current problems in an area of law which applies to all of Canada, I have quoted from it extensively, at page 711 of the report and following:

"By traditional criteria, there is no question that Mr. Junor was alive when his kidneys were removed. Traditionally, both law and medicine have been unanimous in saying that it is not safe to pronounce a man dead until after his vital functions have ceased to operate. The heart has always been regarded as a vital organ.

Since the introduction of organ transplantation, however, many physicians and moralists have sought to establish new and different criteria for determining the time and the fact of death.

It is apparent that the fresher the kidneys, the better chance the recipient will have. It is apparent that in the case of a heart transplant there is no use transplanting a dead heart. The heart must be alive if the recipient of it is to have any chance of life. The problem facing medicine and society in recent years is: How do you get a living heart out of a dead body? If a person is not dead until after his heart ceases to function, it is practically impossible to imagine a successful heart transplant except by taking a living heart out of a still living person. But this is abhorrent to the conscience of many people.

So a substantial body of medical opinion has come forward with the suggestion that the concept of death itself should be redefined.

Some have said, if a man is "as good as dead", we will call him "dead" and then there will be no ethical problem about taking out his vital ogans.

Some doctors have said that a person is as good as dead, and is therefore dead, if he is in such a condition that it can be predicted with confidence that he will never again be able to be restored to meaningful life.

Others have advanced the proposition that death is not an event but a process and when the process of death reaches a stage where a doctor is of the opinion that the processs is irreversible the person should be declared dead.

Dr. Tweed advanced this view in this case before the jury and the learned trial judge appears to have adoped it for he said to the jury, "It appears that death is a process, not an event, as I stated earlier."

This is a most controversial statement, at variance with centuries of religious tradition. It is a statement vigorously disputed in many medico-legal books, for example, in Grey's Attorney's Textbook of Medicine, (3d) 1975 (Supp.), vol. 1B, para. 29.11. Religion has taught us that death is an event. Dying may be process, but death is an event. Except for some small sects, such as those in Rumania, who believe that death is a process during which the soul is in a state of suspended animation (hence perhaps residing in vampire bats), the overwhelming weight of religious teaching all over the world is that the moment of death occurs when the soul leaves the body. This is true not only of Christians, who believe in the personal immortality of the individual soul and the immediacy of judgement after death, but also of

eastern religions which believe in the transmigration of souls at the moment of death.

Furthermore, by common consent, it has been held by all civilized people that no one, for however laudable a purpose, has the right to dispatch a dying man so as to hasten his death. Most moralists agree that it is not wrong to withhold extraordinary treatment to prolong the life of a dying man. It is not wrong to let him die. But directly to dispatch him by cutting out his heart or his lungs or his kidneys is contrary to every principle of civilized morality, as held by large numbers of citizens.

Another large body of medical opinion, I think the most substantial body, accepts the fact that death is an event and not a process. They say that the critieria for "defining" death are really criteria for determining the manifestations of death. It is true that the fact of death is manifested where all the vital signs, including heartbeat, have ceased. But, they say, it is equally true that the fact of death is manifested if all activity of the brain has ceased for a sufficient period of time. If the brain of a man is dead, then it is safe to say that the whole man is dead. It is the activitis operated through the brain which differentiate man from an animal. If the brain is dead, he is dead.

This approach has gained widespread support not only among doctors but among moralists as well and has received legislative recognition in some states and in the Province of Manitoba.

This opinion does not proceed on the principle that if a man will surely die, then it is safe to call him already dead. It operates on the principle that, if a man's brain is dead, he is dead.

The trouble is that it is not always obvious when brain death occurs. There are well documented cases where a man's brain has shown absolutely no sign of activity for two days or more and yet he has recovered and survived. This is particularly so where a man has ingested large quantities of central nervous system depressants such as barbituates.

There has been a great deal of debate about this subject and the debate is likely to go on for some time.

Many eminent physicians, including an ad hoc committee of doctors of Harvard University, have established certain criteria for determining brain death. Among the requirements are flat E.E.G.'s taken 24 hours apart. The possibility of barbituate consumption being excluded, they say that if there is no sign of brain activity during a 24-hour period, it is then safe to say the brain is dead and hence that the man is dead.

In the case of the deceased, Mr. Junor, the Harvard criteria were not followed. Twenty-four hours before the kidney transplant there was evidence of brain stem activity. Neither were the criteria proposed by Cornell University doctors followed.

Faced with the difficulties inherent in establishing universally accepted criteria for determining brain death, many doctors have said that the safe course is to have at least two doctors certify death before allowing removal of vital organs.[20]

Thus, a world assembly on medicine held in Australia in 1968 said, "If transplantation of an organ is involved, the decision that death exists should be made by two or more physicians, and the physician determining the moment of death should in no way be immediately concerned with the performance of the transplantation."

Many hospitals have regulations requiring such certificates of death prior to removal of vital organs. According to the evidence, the Health Sciences Centre has no such protection for potential donors.

These questions are important and they may have to be considered by the courts some day. In my opinion, however, they were not properly before the court in the case before us.

The legal and ethical implications of the conduct of doctors are no doubt under constant and careful review by peer review committees, by the College of Physicians and Surgeons, and by others.

I think it is regrettable that the doctors at Health Sciences Centre were subjected to the lengthy questioning in this case. I do not think that the trial in this case, or in cases similar to it, affords a suitable forum for discussing these important questions.

I think that counsel for the accused proceeded on a fundamental misconception of the law. They assumed that, if it could be shown that death resulted in this case from the removal of the kidneys, then the accused should be acquitted because there would be a reasonable doubt that they had been the cause of death.

The assumption underlying counsel's conduct in this case is that there can be only one cause of death. I think the law is that the conduct of a defendant in a criminal trial need not be shown to be the sole or "the effective" cause of a crime. It is sufficient if it is a cause."

A review of the Kitching and Adams decision does not suggest any *legal* reason which would prevent brain dead donors from being transported to or admitted to a hospital. Indeed the Kitching and Adams decision makes it clear that under the criminal law of Canada donation of organs does not raise a reasonable doubt that a defendent is *a* cause of death.

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[20]In Alberta, Section 7 of the Human Tissue Gift Act requires that death be certified by at least two doctors before transplantation may take place. Manitoba does not have this provision in their Human Tissue Act.

Discussion and Analysis

While a donor patient may be considered brain dead or medically dead, administrative difficulties may occur if the donor on organ support systems is declared dead before admission to the transplant hospital. The situation is difficult because hospitals are reluctant to admit legally dead patients, and transport is restricted by public health laws and regulations on the removal and transportation of dead bodies, (regulations regarding the transport of bodies affected by specific communicable diseases discussed are above).

Technically, the above legislation might apply to a donor patient on organ support if a death certificate has been signed before transport but in practice, the potential donor is treated as a patient and transported as such, since the time of death in Alberta is stated as the time when mechanized support is discontinued. While this may seem reasonable at first glance, it leads to a double standard with regard to declaration of death and organ transplants. On the one hand, the patient is brain dead or dead for medical purposes and could be a possible organ donor and on the other hand the patient is legally alive for purposes of transportation and hospital admission.

APPENDIX L.2

A MEDICAL VIEW ON THE DEFINITION AND DETERMINATION OF BRAIN DEATH

by
John B. Dossetor
September 25, 1985

The Task Force considered the importance of proper terminology to define certain aspects of death and dying, in light of recent medical developments regarding brain death and brain stem death. Consensus was obtained on the following matters:

1. a definition of death;

2. the definition(s) of brain death;

3. the determination of death;

4. awareness of the U.K. position as regards brain stem death, and how this might differ from the North American 'definition(s) of brain death';

5. awareness of the problems in dealing with brain dead donors and why it is necessary to avoid letting others conclude that medical opinion is that they are still in some degree alive;

6. implications of these facts on prospective transfer, ambulance transportation, hospital admission and discharge policies.

1. A Definition of Death

Death is not defined except as being the state of a person in whom life has ceased. Legally, a person is dead when a duly qualified and licensed medical practioner declares that the person is dead.

At such a moment that person ceases to be a person and becomes a dead body, or cadaver. In the Task Force document the word 'donor' has been used for the expression 'brain dead donor', even though a dead body is not capable of donating anything. The expression 'brain dead donor' is more acceptable, albeit an euphemism for the correct expression: brain dead body.

2. A Definition of Brain Death

Manitoba is the only Canadian province which has a legal definition of death, but there has been a movement in other jurisdictions to obtain agreement on this matter. In particular, in the USA, there has been a recommendation for a Uniform Determination of Death Act (12 Uniform Laws Annotated, 1985, Cumulative Addition) in which the determination of death would be defined as:

> "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A

determination of death must be made in accordance with accepted medical standards."

3. The Determination of Death

The determination of death (rather than its definition) is carefully described in Section 7(1) of the Human Tissue Gift Act, R.S.A. 1980, c.H-12, as follows: "for the purposes of a post-mortem transplant, the fact of death is determined by at least two physicians in accordance with 'accepted medical practice'", and that is all.

Accepted medical practice in Alberta recognises that death has occurred when there is **irreversible cessation of function of the whole brain.** In Manitoba, this is codified in their Vital Statistics Act. In most instances, in those dying of most chronic disease processes, death of the brain occurs within minutes after cessation of spontaneous action of the heart or spontaneous breathing. In the remaining instances, but always in circumstances where cardio-resuscitation has been practiced, brain death can occur prior to cessation of spontaneous heart action (though never prior to cessation of spontaneous respiration). It is in these situations that determination of death in accordance with accepted medical medical practice needs to be thought through, specifically.

4. Brain Death and Brain Stem Death

In North America, most neurologists and neurosurgeons accept that irreversible loss of function of the whole brain can be safely diagnosed in patients **who have not become comatose from drugs, hypothermia or metabolic causes,** though there are different opinions on the importance to be attributed to the passage of time alone, and to the EEG in making this diagnosis.

In the UK, the diagnosis of 'brain stem death' is made when there is irreversible loss of all functions of the brain stem, again **only in those who have not become comatose from drugs, hypothermia or metabolic cause.** They insist that determination of death, as brain stem death, is a clinical diagnosis (using carefully delineated tests of brain-stem function, including a 10 minute apneic test after 5 minutes ventilation with an inspired gas mixture of 95% O2 and 5% CO2). In the UK there is no requirement for angiography or EEG tracings. UK neurologists point out that consciousness is impossible if the brain stem reticular activating function is lost. Dr Pallis[21] also points out that one cannot test for higher brain functions in an unconscious patient apart from appreciation of pain, but one can test rigorously for brain stem functions and, in appropriately selected subjects, the patient is not dead if there is a trace of any brain stem function.

5. Brain Dead Donors

For patients on life-support systems when two physicians, using accepted medical practice, have determined that brain death has occurred, the former person becomes a dead body, or cadaver, on organ-support systems. The time of determination of death is recorded in the hospital chart. It does not matter when the death certificate is actually signed (and in practice this is often not done until

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[21]Pallis, C. British Medical Journal 1983 (ISBN 0 7279 09099 4) Devonshire Press

the following day) though the time of death on the certificate should be the same time as was previously recorded in the chart.

There is no such thing as being medically dead, but not legally dead. Also, although the grosser forms of physical decay of the body (it's organic degradation and putrefaction) do not occur on organ support systems, one should not overlook the fact that organic degradation is occurring in the brain. It starts at or before the time at which death was determined. It is usually in the form of colliquative necrosis, or liquefaction, of the brain tissue. This form of necrosis does not produce changes which can be appreciated by sight, hearing or sense of smell of observers.

To illustrate the inapparent aspects of this form of necrosis, a report in the British Medical Journal of April 1985 cites the case where a pregnancy was continued for 10 weeks after a woman sustained an intracerebral hemorrhage which caused her death. The body was maintained on organ support systems until a live fetus was delivered by Casesarian section. The blood pressure could not be maintained thereafter and body's circulation ceased. At autopsy, there was no brain tissue (only fluid) and the brain stem had also liquified. It was possible to see the site of bleeding from an artery at the base of the brain which had led to the increase of intra-cerebral pressure which had, in turn, led to cessation of brain blood flow and death of the brain, many weeks earlier.

It is worthy of comment that this case was presented in the British Medical Journal as if the 'mother' was 'alive' all through the 10 week period and then 'died' after 'her delivery'. It is my personal opinion there would have been an editorial policy for this deception. It is also of interest, in this case, to speculate how it was possible to maintain organ support, with circulation, through such a long period after death. The authors of the article speculate that this unusual aspect was due to the hormonal secretion of the placenta; this organ may secrete enough 'pressor amines' or other products to enable the maintenance of vasomotor tone for such a long period of post-mortem continuance of circulation.

6. Administrative Policies

Once brain death has been determined, and with appropriate consent, the organs and tissues from the body can be used for transplantation. For this to be effected, the body may have to be transferred by ambulance (because it still should be maintained on organ support systems and these are not otherwise provided) for subsequent admission to a transplant hospital. It may even be (and usually is) placed on the same ward as patients. Organs from that body also have to be removed in operating rooms normally used for patients.

It is the use of these facilities for dead bodies that requires some new regulations.

APPENDIX M

A LEGAL ANALYSIS OF THE DISPOSAL OF HUMAN TISSUE

Janice E. Trylinski, M.Sc., LL.B.

November 21, 1984

Introduction

Medical personnel at the University of Alberta Hospital have suggested that the incineration of human tissue after autopsy may not be an appropriate method of disposal. For example, accurate neuropathological examination of the brains and spinal cords of deceased patients can only be performed if the specimens are fixed in formaldehyde for 2 weeks prior to examination. This precludes the return of such specimens to the body at the completion of the general autopsy which normally takes place one to several hours after the death of the patient. The body is then released for burial without the brain tissue. The brain tissue is later disposed of by incineration at the Mackenzie Health Sciences Centre.

Pathologists are concerned that the bereaved next-of-kin might be upset to learn that the deceased was buried without his brain or spinal cord and that the tissue was subsequently incinerated. This concern is based on an incident in Ontario where next-of-kin had a body exhumed and examined because they thought it was not buried in a complete state. The body was missing certain organs and the family was extremely upset.

Although s. 44(1)(f) of the Hospitals Act, R.S.A. 1980, c. H-11 and s. 68(d) of the Mental Health Act, R.S.A. 1980, c. M-13 permit the Lieutenant Governor in Council to make regulations regarding "the disposal of human tissue, whether removed during an operation, autopsy or otherwise", there are no regulations regarding the manner of human tissue disposal.

Section 9(2) of the Mental Health Regulations, A.R. 346/82, also touches on the problem of the disposal of human tissue but refers back to the Hospitals Act and Regulations as it states that: "A Board shall comply with the Hospitals Act and regulations under that Act in the disposal of human tissue." There is also legislation which directs pathologists to examine certain tissue, s. 22(1) of the Operation of Approved Hospitals Regulations, A.R. 146/71, as amended which states that: "All tissue removed at operation, with the exception of those listed in (5), shall be forwarded to a pathologist registered in that specialty in the province." Section 10(1) under the Fatality Inquiries Regulations, A.R. 120/77 as amended, provides that tissue or fluid be stored for a certain length of time:

> "Where tissue or fluid is removed from a body by a medical examiner or a pathologist in the course of an examination or autopsy as the case may be, the tissue or fluid shall be retained for at least three months."

Section 10(4) of the same regulation authorizes disposal of certain tissue but does not speak about the manner of disposal:

> "Notwithstanding subsection(1) or (2) where tissue are retained for

purposes of historical investigation and paraffin blocks have been prepared from the the tissue, the tissue may be destroyed by the pathologist who performed the autopsy or by any other person authorized by the Chief Medical Examiner."

It has been brought to the attention of the Task Force that the manner of human tissue disposal is not covered by regulation and the question has been raised regarding appropriate regulation.

In order to put the concerns of medical personnel into perspective it should be noted that s. 178 of the Criminal Code of Canada makes it an offence to neglect to bury or to interfere with a human body or human remains. While this section of the Criminal Code deals with an extreme situation it is an important indication that the law takes a dim view of improper behaviour with regard to dead bodies.

Section 178 of the Criminal Code states that:

"Everyone who
(a) neglects, without lawful excuse, to perform any duty that is imposed upon him by law or that he undertakes with reference to the burial of a dead human body or human remains,
or
(b) improperly or indecently interferes with or offers any indiginity to a dead human body or human remains, whether buried or not, is guilty of an indictable offence and is liable to imprisonment for five years."

While it might be argued that an autopsy could be considered as an indignity to a dead human body, there are no reported Canadian cases where convictions, or even charges have been brought in these circumstances. The only case under this section is that of R. v. Ladue, (1965), 4 C.C.C. 264, 51 W.W.R. 175 (Y.T.C.A.), which deals with intercourse with a dead body, s. 178(b).

The Common Law

The common law regarding treatment of the dead and autopsies is well set out in this remarkably clear excerpt from an article by Professor Bowker, "Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code", 1973 McGill Law Journal, vol. 19, no. 2, 161 at 185.

"What is the common law on these matters? No one could own a dead body and from this consequence grew the rule that a person could not make a binding disposition of his cadaver after death. The latter rule is a non sequitur. Even if a cadaver is incapable of ownership it should not follow that a living person cannot make binding directions on the disposal of his body after death. However, the rule is firmly entrenched.

It is accompanied by another rule having to do with burial. In Blackstone's words, the executor had a duty "to bury the deceased in the manner suitable to the estate which he leaves behind him". (2 Bl.

Comm. 507) This duty became converted into a right vested in the executor or the family. These rights are hard to define. For example, does the family have a cause of action when an unauthorised autopsy has been performed? An Alberta case, Edmonds v. Armstrong Funeral Home, ((1931) 1 D.L.R. 676), held that those responsible for the burial have certain rights over the body. From this the court went on to find that the unauthorised autopsy was an infringement of these rights. In truth the court was seeking a theory on which to found an award for compensation for the family's injured feelings. Prior to the Alberta decision, a Quebec case (Phillips v. Montreal General Hospital 1908, 33 C.S. 483) had reached the same result in an action by the widow."

The Case Law, a Comparative Approach

There are no Canadian cases on consent to retention of tissue at autopsy and on disposal of that tissue after pathological examination. This review is limited to American case law and while American decisions are not binding on Canadian courts, they are especially helpful and very persuasive in the absence of Canadian decisions.

In the United States, it is accepted law that a civil cause of action exists for the wrongful mutilation of the body of a dead person. The basis of such an action is interference with the right of the family (spouse or next-of-kin), to bury the body in the condition in which it was found when the deceased died. A plaintiff may establish a cause of action for wrongful autopsy by showing that although authorized, the autopsy exceeded the scope of the authorizatiion or was performed in a generally negligent or improper manner.

Although a cause of action for wrongful mutilation of a dead body does not exist in Canadian civil law, Canadian courts permit recovery in negligence when the damage caused is nervous shock. It is then possible that a family member could make a claim that the autopsy was negligently performed and that he or she suffered nervous shock after seeing the mutilated body of the deceased. In other words Canadian counsel can achieve the same result as their American counterparts by using a negligence action. Although there may be difficulties in establishing proof of nervous shock and at one time it was thought that nervous shock must be accompanied by some physical symptoms, Canadian courts are now more generous in permitting recovery as long as the plaintiff is suffering a recognizable psychiatric illness. Generally reports from two independent psychiatrists outlining genuine illness are considered to be good evidence of nervous shock.

It is important to remember that while an exact legal equivalent may not exist between the United States and Canada, the mechanisms of recovery are similar and the solutions reached by courts in the United States may suggest directions which Canadian counsel could take to forestall legal action.

Retention of Tissues/Organs as Part of the Autopsy Process

Where consent is required to perform an autopsy and is obtained, the American courts have held that it is reasonable to expect that the autopsy will be performed in the approved and usual professional manner. Whether retention of

tissue or organs is part of that process depends on the facts of each case.

It can be concluded that the courts will interpret a consent to autopsy to include the retention of tissue and organs if the autopsy is performed in the approved and usual professional manner and even if the consent is limited, the body may be thoroughly examined as long as the limitations are observed (Winkler v. Hawkes, 102 N.W. 418). Recent case law suggests that if the consent to autopsy form includes authorization to keep pathological specimens, no claim can later be made for the retention of organs (Lashbrook v. Barnes, 437 S.W.2d 502) and that a body is not mutilated by autopsy if the brain is replaced in the stomach for burial where the evidence is that the autopsy was performed in the customary and usual professional manner (Lashbrook v. Barnes). Further, even where the courts have recognised the possibility that the family had a right to the return of the removed organs (Gray v. Southern Pacific Co., 68 P.2d 1011, and Hendricksen v. Roosevelt Hospital, 297 F.Supp. 1142) violation of such a right could give rise to no more than nominal damages (Gray v. Southern Pacific Co., 68 P.2d 1011).

Disposal of Retained Tissues/Organs by Incineration

There are only two case dealing with the disposal of retained tissue by incineration. They stand for the proposition that absent any specific direction by the patient (Browning v. Norton Children's Hospital, 504 S.W.2d 713), disposal of human tissue or body fragments by the usual hospital custom of incineration does not give rise to an action for damages (Doxtator, 79 N.W. 922 and Browning).

Difficulties with a Legislative Solution

Since s. 44 of the Hospitals Act permits regulation regarding the disposal of human tissue and since regulations under that Act already exist for forwarding tissue to pathologists, the Hospitals Act is a likely place to add regulations regarding the disposal of human tissue. However, the decision to go forward with legislation/regulation regarding the disposal of human tissue, after autopsy, surgery or otherwise, may pose problems.

How shall we define tissue? The definition of tissue under s. 1(b) of the Human Tissue Gift Act includes organs but does not include any naturally regenerable tissue such as skin, bone, blood, blood constituents and so on. This was a calculated legal decision made so that it would not interfere with donations of blood and other regenerable tissue carried out daily in Canada. Otherwise, signed consent forms would be required in these now routine donations. Also it was reasoned that only donation of vital organs required this special protection of the law since those donations were potentially life threatening. If the term "human remains" is used instead of human tissue, problems also arise with the application of the Cemetaries Act, R.S.A. 1980, C.F-6, the Fatality Inquiries Act and s. 178 of the Criminal Code all of which legislate regarding human remains.

If problems of definition are resolved then the scope of the proposed legislation/regulation must also be considered. Should disposal of tissue from autopsies done under the Fatality Inquiries Act on the premises of the Chief Medical Examiner also be included in this regulation? Does this require additional regulation under the Fatality Inquiries Act?

Proposed Legislative Solutions

If a legislative solution is required, s. 44(1)(f) of the Hospitals Act and s. 49(c) of the Fatality Inquiries Act provide a mechanism and the following model is suggested:

Disposal of Tissue Removed During An Operation, Autopsy or Otherwise

Human tissue and waste items shall be disposed of in such a manner as to minimize any hazard to personnel or to the environment. Dignified and proper disposal procedures shall be used in accordance with the bylaws of (substitute the name of the appropriate facility).

However before such a solution is implemented it is necessary that hospital by-laws, operating procedures, laboratory manuals, etc. be examined for conflicts which might occur with established procedures. For example, the Infection Control Guidelines prepared by the Joint Committee on Infection Control of the Alberta Hospital Association and the Alberta Medical Association, September 1983 in Phase VI, Disposal of Waste from Hospitals and Health Care Centres, sets out guidelines for the disposal of miscellaneous wastes which are defined as "Includes tissue removed at operation or tissue passed and received in the laboratory." There would certainly be overlap between the proposed legislation and the infection control guidelines. It is suggested that overlap and possible conflict with other hospital procedures may also exist.

Conclusions

American case law indicates that a general autopsy performed in the approved and usual professional manner will include the removal and retention of organs or parts thereof for microscopic examination. However, the courts balance this against the right of the family to receive for burial, a body which is not mutilated by autopsy. Similarly, absent any direction by the patient or his family regarding disposal of tissue, no liability will be incurred for the usual and proper disposal of tissue.

Since Canadian courts recognise recovery for nervous shock and since they have permitted recovery for unauthorised autopsy, it is likely that they would consider making awards for nervous shock suffered in relation to retention and disposal of tissue at and after autopsy, if the circumstances warranted.

Legislation or regulation is not required at this time. Physicians and hospitals will be afforded more than adequate protection from the legal difficulties discussed above if:

1. Hospital consent forms are broadened to include authorization for retention of tissue/organs as part of the autopsy process;

2. Additional authorization is obtained when extensive examination and retention of tissue and organs is required;

3. Hospital by-laws or laboratory procedures include directions for the proper and dignified disposal of human tissue in a manner which is not hazardous to personnel or the environment.

However, if a legislative solution is desired, s. 44(1)(f) of the Hospitals Act and s. 49(c) of the Fatality Inquiries Act provide a mechanism for regulation and the following model is proposed:

"Disposal of Tissue Removed During An Operation, Autopsy or Otherwise

Human tissue and waste items shall be disposed of in such a manner as to minimize any hazard to personnel or to the environment. Dignified and proper disposal procedures shall be used in accordance with the bylaws of (substitute the name of the appropriate facility)."

Any legislative solution should also deal satisfactorily with the definition of tissue or human remains so that there is no conflict with the Human Tissue Gift Act, the Cemetaries Act, the Fatality Inquiries Act and s. 178 of the Criminal Code.

CASE LIST

CANADIAN CASE LAW

R. v. Ladue, (1965) 4 C.C.C. 264, 51 W.W.R. 175
Edmonds v. Armstrong Funeral Home, (1931) 1 D.L.R. 676.
Phillips v. Montreal General Hospital (1908), 33 C.S. 483.

AMERICAN CASE LAW

Winkler v. Hawkes & Acker, 102 NW 418.
Gray v. Southern Pacific Co., 68 P.2d 1011.
Lashbrook v. Barnes, 437 S.W.2d 502.
Hendricksen v. Roosevelt Hospital, 297 F.Supp. 1142.
Doxtator v. Chicago & W.M. Ry. Co., 79 N.W. 922.
Browning v. Norton Children"s Hospital, 504 S.W.2d 713.

APPENDIX N

A LEGAL ANALYSIS OF ENUCLEATION OF EYES BY NON-PHYSICIANS AND RESPONSIBILITY FOR DONOR SELECTION IN CORNEAL TRANSPLANTS

Janice E. Trylinski, M.Sc., LL.B.

March 20, 1985

Introduction

The Surgical Procedure of Enucleation

Enucleation is a procedure whereby the eye is surgically removed under aseptic conditions. At the present time in Alberta the procedure is performed by residents in opthalmology and opthalmologists. In Edmonton, opthalmology residents enucleate the eye, review the patient's chart and make the preliminary assessment for donor suitability. The surgeon then makes his own physical examination of the donor eye. Based on his own examination of the donor eye and the preliminary work of the resident, the surgeon decides whether the eye is suitable donor material or not.

In some centres in the United States this procedure is performed by trained technicians operating under the supervision of a physician. In the state of Texas, Article 4590-5, sections 1-4, of the Texas Public Health Code (see Addendum 1) authorizes eye enucleations when the eye is an anatomical gift. Those legally capable of enucleating an eye under the Texas law are: a licenced physician or surgeon, a licenced doctor of dental surgery or medical dentistry, a licenced embalmer, or a technician supervised by a physician or surgeon. With the exception of licenced physicians, all persons performing eye enucleations are required to take a course on eye enucleation which meets certain standards set by law.

The United States Navy[22] uses specially trained teams of four or five surgical technicians for tissue procurement. The team is available at all times and works under the direction of a physician. It removes tissue; labels and records blood, tissue and tissue cultures generated during the operation; and ends the procedure with a reconstruction of the cadaver. Processing is done by technicians using standard aseptic operating room techniques.

Donor Selection Criteria

Two dramatic reports of death resulting from the implant of infected corneas, highlight the importance of stringent donor selection criteria.

In a letter to the editor of the New England Journal of Medicine, N.E.J.M. (1974) vol. 290, no. 12, 692-693, Drs. Duffy *et al.* document the transmission of Creutzfeldt-Jakob disease, a progressive and fatal disease of the central nervous system, by a corneal transplant.

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[22]G.E. Friedlaender, "Personnel and Equipment Required for A 'Complete' Tissue Bank" (1976) *Tissue Banking for Transplantation* 237

In this case the donor was a 55 year old man. A corneal transplant was performed with donor tissue from this patient shortly after death and before Creutzfeldt-Jakob disease was diagnosed at autopsy. The unfortunate recipient of this cornea was a 55 year old woman who developed symptoms of Creutzfeldt-Jakob disease 18 months after transplant and died 26 months after the transplant. Autopsy on the recipient showed changes characteristic of Creutzfeldt-Jakob disease but the lesions were more severe than in the donor and affected the cerebral cortex, basal ganglion, and cerebellum.

The authors concluded that that occurrence of this rare disease in both the donor and recipient of a corneal transplant suggested a cause and effect relationship that has wider implications in transplantation programs with respect to the transmission of slow-virus disease.

In the case of "Human-to-Human" Transmission of Rabies Virus by Corneal Transplant", N.E.J.M.(1979), vol. 300, no. 11, 603-604, reported by Houff *et al.*, a 39 year old forester-rancher from Idaho died 16 days after a hospital admission. His right cornea was donated to a 37 year old woman who developed a headache and pains in her neck, and shoulder numbness about four and one-half weeks after surgery. She was admitted to hospital and died 50 days after corneal transplantation.

Pathological examination of both donor and recipient tissue was conducted. Rabies virus was detected by immunofluoresence in the temporal lobe of the recipient. Rabies virus was then demonstrated in the donor and recipient eyes. The authors concluded that tissue from patients with post-infectious polyneuritis, or tissue from patients with a neurological disease of suspected viral origin should not be used for organ donation.

In Edmonton, the donor screening criteria of the July 29, 1982 resolution of the Eye Bank Committee of the Canadian Opthalmological Society are used (see Addendum B). The Chief Medical Examiner's Office in Alberta uses similar screening criteria. Both methods of donor screening are comprehensive and reject tissue from patients with rabies, Creutzfeldt-Jakob disease and other neurological diseases.

In Calgary, some physicians use donor material provided from agencies in the United States. Presumably those agencies apply similar criteria in donor selection.

The Law

The Role of the Technician

Enucleation, or the surgical removal of an eye, is a procedure which may be characterized as the practise of medicine. The practise of medicine is regulated by the Medical Professions Act, R.S.A. 1980, c. M-12, and is restricted to registered practitioners. There are exceptions to this restriction in the Medical Professions Act for: for students enrolled as professional medical assistants, s. 76(3); for emergency medical care (the "good samaritan"), s. 78(1); and for persons practising a profession or calling under the authority of a general or special act of the legislature, s. 78(2). Persons practising under legislative authority could be: emergency medical technicians-paramedics; respiratory technologists; medical radiation technologists; nursing assistants; rehabilitation practitioners; acupuncturists (the above all under the authority of the Health Occupations Act, R.S.A. 1980, c. H-5.1, as amended); registered nurses; registered physiotherapists; or occupational hygienists.

In addition to legislative authority, technicians commonly carry out basic medical procedures in which they have been trained when operating under the authority of a physician.

In summary, a technician in Alberta (operating with or without legislative authority) may enucleate eyes when doing so under a physician's authority.

While enucleation may be carried out by technicians operating under a physician's authority it is doubtful legally whether the technician could determine donor suitability. Determination of donor suitablity is similar to making a differential diagnosis. As such, it is a decision which the technician has neither the training or judgement to make. It is improper for a physician to expect a technician to possess this expertise or to assume this responsibility.

The Case Law

There are only two reported cases dealing with negligence and cornea transplants in both the Canadian and American law reports and both cases are American.

The first case, McDermott v. Manhatten Eye, Ear and Throat Hospital, 270 N.Y.S. 2d 955, a 1966 decision of the New York Supreme Court Appellate Division was a malpractice action arising out of a cornea transplant operation. The Court held that the operation which had an unsuccessful result was not negligently performed and that the operation was not contraindicated. This case is distinguishable on its facts. It deals with an unsuccessful surgical result which was not caused by surgical negligence or negligent cornea selection.

The case of Ravenis v. Detroit General Hospital, 234 N.W.2d 411, a 1975 decision of the Michigan Court of Appeals was an appeal from the trial decision in which a jury found the Detroit General Hospital negligent in its method of corneal donor selection.

On appeal, Walsh J. speaking for the court, held that the fact that the hospital's first year opthalmology resident who removed the donor eyes was not negligent did not preclude a finding of negligence on the part of the hospital for its method of donor selection. The fact that the hospital had failed to maintain complete records showing the medical history of the donor was negligent. The hospital was also held to be negligent because they did not meet the standard of care imposed on a hospital in selecting eye donors for transplants.

The fact that the surgeon was not found to be negligent is puzzling. Since the enucleation and cornea donation were done the Detroit General Hospital and the surgery was performed at the Harper Hospital it may be that the surgeon was able to rely on the Detroit General Hospital to determine donor suitability. Unfortunately, the case is silent on this point. However, it is likely that this case may now be distinguished on its facts because knowledge of donor criteria requirements has increased. Both reports of death from infected cornea implants occurred after this incident. The effect of Ravenis and the reports in the medical literature is to require that the surgeon be certain that donor selection criteria are properly applied at the donor source.

In Alberta because of the C.O.S. statement with respect to the surgeon's assumption of responsibility, it is unlikely that a surgeon in Alberta could rely on

his source of corneas without determining that the donor source had proper screening procedures and criteria in place.

Discussion

The Application of Donor Screening Criteria, Who is Liable?

If there is some confusion in the application of the donor selection criteria so that a patient suffers damage as a result, all parties involved in the donor selection and transplantation process may be held responsible.

The employer is held responsible for the employee's act under the doctrine of vicarious liability. Depending on the facts of the case, the employer could be the institution or the physician and the physician could either be the employer or the employee. The fact that the employer or institution may be held liable for the negligent act does not protect the employee in court. Both the employer and employee will be held responsible for the wrongful act. This is known as joint and several liability and it means that both or either may be held responsible for the act. This doctrine provides the injured party with almost certain recovery against someone in the event that the damage was caused by negligence. In practice, both employer and employee would be sued and the employer's insurers would pay the damages. The employer through his insurers would then attempt to recover the damages paid to the injured party from his employee's insurers. If the injured person sues only one party (employee or employer) the other party may be brought into the law suit as a co-defendant by the party originally sued.

A hospital will also be held liable for non-employee physicians because it has a duty to review the qualifications of the physicians. Thus a hospital will be held liable if it knew or ought to have known that a doctor lacked the skill, knowledge or judgment to carry out the medical treatment for which the hospital granted privileges.

In addition to the general principles of law discussed above the following statement in the July 29, 1982 resolution of the Eye Bank Committee of the Canadian Opthalmological Society, which appears in capitals in the original document, should be noted (see Addendum 2): "THE ULTIMATE DECISION TO ACCEPT OR REJECT THE DONOR CORNEAL MATERIAL OFFERED, AND THE SUBSEQUENT USE OF THIS MATERIAL IS THE RESPONSIBILITY AND DECISION OF THE OPERATING SURGEON".

The effect of this statement is that the surgeon is ultimately responsible for donor selection. Consequently, the surgeon must be satisfied not only that the donor material was screened and found acceptable by the Canadian Opthalmological Society criteria (or equivalent) but that the screening was properly performed.

Conclusion

In Alberta the responsibility for the proper application of donor selection criteria lies primarily with the surgeon. If the surgeon choses to accept donor material he must be certain that this material meets the Canadian Opthalmological Society criteria and that the donor screening has been properly performed. The same standard will apply to out-of-province donor material. In the event that out-of-province donor material was found to be the source of infection or illness it is likely that the injured party would restrict his claim to persons in the province

i.e., the surgeon and the hospital. The surgeon and hospital would be able to seek recovery from the out-of-province donor source but since this source would be outside the jurisdiction recovery would be difficult and expensive.

There is nothing in the law in Alberta which restricts a physician from instructing a technician to perform certain procedures under his (the physician's) authority. If a physician wishes to have his technician enucleate eyes for corneal transplants he should ensure that the technician receives proper training at a recognised centre and that guidelines and procedures to be followed are reviewed by the physician's governing body. These guidelines should address quality control and monitoring of the program by an external body and should include a description of the technician's activities. The technician's activities could include gathering data on the proposed donor but should not include the determination of donor suitability.

CASE LIST

McDermott v. Manhatten Eye, Ear and Throat Hospital, 270 N.Y.S. 2d 955.

Ravenis v. Detroit General Hospital, 234 N.W.2d 411.

ADDENDUM 1

(Texas Public Health Code. Article 4590-5, Sections 1-4.)

Art. 4590-5 Eye enucleation for anatomical donations

Persons who may enucleate eyes as anatomical gift

Section 1. Only the following persons may enucleate an eye when an eye is an anatomical gift:
1) a licenced physician or surgeon;
2) a licenced doctor of dental surgery or medical dentistry;
3) a licenced embalmer; or
4) a technician supervised by a physician or surgeon.

Eye enucleation course

Section 2 All persons, except licenced physicians, who perform eye enucleations must complete a course in eye enucleation that is taught by an ophthalmologist as defined in this Act and must possess a certificate showing the fulfillment of this requirement.

Requisities of the course

Section 3 The course must include anatomy and physiology of the eye, instruction in maintaining a sterile field during the procedure, use of the appropriate instruments, and sterile procedures for removing the corneal button and preserving it in a preservation fluid.

"Ophthalmologist" defined

Section 4 "Ophthalmologist" means for the limited purpose of this Act one licenced to practice medicine who specializes in the treatment of diseases of the eye.

ADDENDUM 2

RESOLUTION OF THE EYE BANK COMMITTEE OF THE CANADIAN OPHTHALMOLOGICAL SOCIETY, JULY 29, 1982

The Eye Bank Committee of the Canadian Ophthalmological Society (C.O.S.) proposes to the council of the C.O.S. that the following resolution be passed:

Moved by Dr. Hassard, seconded by Dr. Dube, that surgical donor corneal tissue be screened according to the standards of the Eye Bank of America and that for Penetrating Keratoplasty "the basis for rejection of donor corneal material is divided into two categories:

1. Tissue which may represent a health threatening condition for the recipient or be contra-indicated because of endothelial dysfunction.

    a. Death of unknown cause
    b. Death from central nervous system of unknown etiology
    c. Cruetzfeld-Jacob disease
    d. Subacute sclerosing panencephalitis
    e. Congenital rubella
    f. Progressive multifocal leukoencephalopathy
    g. Reyes syndrome
    h. Subacute encephalitis, cytomegalovirus brain infection
    i. Septicemia
    j. Hepatitis
    k. Rabies
    l. Intrinsic eye disease - retinoblastoma, conjunctivitis, iritis, glaucoma, corneal disease (e.g. keratoconus, or pterygium) and malignant tumors of the anterior segment.
    m. Blast form leukemia
    n. Hodgkin's disease
    o. Lymphosarcoma

2. Tissue which may require caution with regard to donor selection.

    a. Multiple sclerosis
    b. Parkinson's disease
    c. Amyotrophic lateral sclerosis
    d. Jaundice - r/o hepatitis
    e. Chronic lymphocytic leukemia
    f. Diabetes
    g. Surgically induced eye abnormality, e.g. aphakia
    h. Syphilis
    i. Acquired immunodeficiency disease*.[23]

The ultimate decision to accept or reject the donor corneal material offered, and the subsequent use of this material is the responsibility and decision of the operating surgeon."

Passed by the C.O.S. Eye Bank Committee, June 29, 1982.

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[23]This was a recent addition to the criteria. See Appendix R.

APPENDIX O

ALBERTA ATTORNEY GENERAL
OFFICE OF THE CHIEF MEDICAL EXAMINER
CORNEAL DONATION PROGRAM
ONE YEAR SURVEY STUDY
August 1, 1984 - July 31, 1985

	CALGARY		EDMNTON		ALBERTA	SUM
Month	No. of Requests	No. of Donations	No. of Requests	No. of Donations	No. of Requests	No. of Donations
Aug/84*	-	-	4	3 (75%)	4	3 (75%)
Sept/84	-	-	14	4 (29%)	14	4 (29%)
Oct/84	-	-	10	4 (40%)	10	4 (40%)
Nov/84	-	-	6	2 (33%)	6	2 (33%)
Dec/84	-	-	6	3 (50%)	6	3 (50%)
Jan/85	-	-	8	3 (38%)	8	3 (38%)
Feb/85**	4	1 (25%)	8	4 (50%)	12	5 (42%)
Mar/85	5	4 (80%)	8	4 (50%)	13	8 (62%)
Apr/85	6	3 (50%)	5	3 (60%)	11	6 (55%)
May/85	4	2 (50%)	12	7 (58%)	16	9 (56%)
Jun/85	5	3 (60%)	8	5 (63%)	13	8 (62%)
Jul/85	8	4 (50%)	1	0 -	9	4 (44%)
TOTAL	32	17	90	42	122	59 (48%)

* The survey in Edmonton office of the Chief Medical Examiner started in August/1984. ** The survey in Calgary Office of the Chief Medical Examiner started in Feb/1985.

Comment

Approximately 10% of the persons receiving official autopsies are suitable for cornea donation, and in about 45% of these cases, consent for donation is given by the families.

Although the program has only been in operation for a short time, it has met with considerable success and to date 90 eyes have been donated in Edmonton. This is a considerable donation since recently released statistics from the CNIB in Edmonton indicate that about 165 persons are on the waiting list for a cornea.

APPENDIX P

CORNEAL DONATION STATISTICS, EDMONTON*

August 1, 1984 to March 31, 1985

	Eyes Donated	Corneas Trans-planted	Teaching and Research	Patients Added to Waiting List	Patients On List at End of Month	Patients Removed from List
April 1984	22	15	7	11		
May	20	6	14**	13		1
June	10	8	2	13	179	3
July	14	11	3	7	174	1
August	10	4	6 to Calgary	5	175	1
September	18	15	3	9	171	
October	14	8	6	10	168	3
November	24	8	16	20	180	
December	20	18	2	10	168***	3
January 1985	16	6	9+1 to Calgary	11	171	1
February	18	7	9+2 to Calgary	9	167	6
March	24	12	10+2 to Calgary	16	170	1

*These figures were kindly supplied by Dr. D.T.R. Hassard.

**2 corneas not suitable for transplantation were disposed of at the request of the family.

*** There was a discrepancy of one patient at the end of December 1984. This arose because a patient requested removal from the list and later asked to be put back on the list. To accommodate patients, they are placed back on the list at approximately the same place on the list.

NOTE: Utilization of eyes appears low because all donations of tissue are accepted regardless of pathology. Tissue unsuitable for transplantation is then used in teaching and research unless the family requests otherwise.

APPENDIX Q

John W. Dahl's Story

My name is John W. Dahl, I am 24 years old and live in Whitecourt, Alberta. I have been asked to write a brief article regarding the manner in which the modern miracle of corneal transplants has changed my life.

I have an heredity eye disease which was passed onto me by my father. The disease is known as Lattic Dystrophy, which causes a gradual clouding of the cornea, resulting in deterioration of vision and eventual blindness. What causes this to occur remains a mystery and to date the only treatment is a corneal transplant. With this type of disorder a transplant lasts an average of approximately eight years. Fortunately for myself and others in my situation it is possible to repeat this treatment as required. My father is a good example of this; he has recently undergone his fifth successful operation.

My visual impairment was quite gradual. It was not until my late teens that I noticed any significant deterioration.

I graduated from high school in June 1979 and entered college in the fall of that year. Due to my failing eyesight I withdrew from college a short time later as I could not longer function adequately in the classroom. I also had to stop driving as my vision continued to deteriorate. I had been aware that I would eventually require corneal transplants, but I had not expected the need to arise so early, my father did not have his first graft until he was 42 years old. At that time all this was depressing me.

Due to the shortage of donors in Alberta I was told the waiting period would be two to three years. It was for this reason I was referred to a surgeon in Toronto. The waiting period in Ontario was much shorter.

I had my first corneal graft in June 1980 and six months later my stitches were removed. I was fitted with contact lenses because glasses could not correct the extensive astigmatism resulting from the surgery. I did not believe my eyes! The deterioration of my cornea had been so gradual I hadn't realized how poor my vision really was. Now, everything was in focus! My father drove me home and I was actually able to read the street signs and license plates. There was also a tremendous improvement in the color of everything, and I could also distinguish the features of people at a distance which had not been I had not been able to do previously. Thinking back to high school, people must have thought I was quite stuck-up, many were unaware of my poor vision.

I used to think I had a problem, and remember thinking "why me?" Since my first transplant I came to realize I didn't have a problem because unlike many others my eyesight can be restored.

I had my second graft in 1983 and have since returned to college and completed my first year. Not only has my vision improved, but I also have much more self-confidence.

I am extremely grateful to: my corneal surgeons and medical personnel; those involved in organ procurement; but mostly to the two persons who upon their death donated their eyes so that my vision could be corrected. I cannot adequately express

in words, my gratitude, for if it were not for these donors I would have eventually lost my sight.

In appreciation I filled out my donor card supplied with my drivers license, donating any needed organs, tissues, or parts. I would urge all of you to do the same, there is no greater gift.

APPENDIX R

AIDS - TRANSFUSION AND TRANSPLANTATION

by

J.M. Turc, M.D., Director

The Canadian Red Cross Blood Transfusion Service
Special Advisor to the Task Force

Introduction

The Acquired Immune Deficiency Syndrome (AIDS) was described in the United States in 1981. Eight months later, in February 1982, the first case of AIDS was reported in Canada.

AIDS was first reported as a disease of severe morbidity and high mortality, affecting homosexual men and intravenous drug abusers. The subsequent development of this syndrome, in patients with hemophilia and recipients of blood transfusions, provided additional suggestions that the cause of the Syndrome was a transmissible infectious agent.

There is now strong evidence that the causactive agent of AIDS is a retrovirus termed lymphadenopathy-associated virus (LAV), human T-cell lymphotropic virus type III (HTLV-III) or AIDS-associated retrovirus (ARV).

As of June 14, 1985, 248 cases of AIDS have been reported in Canada (231 adult and 17 children). Three of these cases involved hemophiliacs, three other have been linked to the utilization of blood products.

AIDS and Transfusion

Epidemiological data, as well as experimental data, now support the concept that the LAV/HTLV-III virus can be transmitted through blood transfusion.

1. In January 1983, the three principal blood banking organizations in the U.S.A., recognized the potential spread of the syndrome through blood transfusion and asked for 1) additional caution in the use of blood and blood products and 2) reasonable attempts to limit blood donations from individuals or groups that may have an unacceptable high risk of AIDS.

2. In March 1983, the Canadian Red Cross requested that members of the group at high risk of developing AIDS, voluntarily exclude themselves from giving blood. This has been the single most salient factor in averting a more serious problem related to the transfusion of infected blood.

3. Following the isolation of the etiologic agent of AIDS, it has been possible to develop enzyme immunoassays, (EIA) to detect the antibody to LAV/HTLV III. In March 1985, the first kit was licensed in the United States and its utilization was immediately implemented in blood banking, to screen blood donors for the LAV/HTLV III antibody.

4. The Canadian Red Cross developed a similar approach on August 1, 1985, the Canadian Blood Committee approved funding for the program implementation. By October 1, 1985, every Transfusion Service in Canada will be testing for LAV/HTLV III antibodies.

Although the prevalence of anti-LAV/HTLV III is not known in the Canadian donor population, initial statistical data released by the American Red Cross, shows that 0.2% of the blood donor population is repeatedly reactive with EIA but that only 0.4% are confirmed positive by "Western Blot".

The "Western Blot" procedure which is rapidly becoming associated with LAV/HTLV III antibody testing is a very delicate two dimensional electropheresis procedure used to isolate and identify proteins. The protein (disrupted AIDS, virus LAV/HTLV III virus) is separated into various molecular weight components using a standard polyacrylamide gel system.

The Western Blot procedure is fairly complex and is performed only by on Canadian Laboratory for LAV/HTLV III antibody testing. It is also very expensive ($100.00 per procedure).

In relation to the situation in Alberta this data would suggest that every year, 200 to 300 units of blood will be EIA reactive and consequently discarded and that 40 donors could have an anti-LAV/HTLV III confirmed by Western Blot.

AIDS and Transplantation

At this date, AIDS has not yet been reported to have been associated with organ or tissue transplants but the transmission of LAV/HTLV III has been established after artificial insemination.

The U.S. Public Health Service has recommended that serum from donors of organs, tissues or semen, intended for human use, be tested for antibodies to LAV/HTLV III and the test results be used to evaluate the appropriate use of such materials (MMWR, May 24, 1985). Furthermore, it is recommended that individuals in groups at high risk for the disease, should not donate organs, tissues or semen, regardless of the results of the antibody tests.

It is very doubtful that an organ or tissue donor self-exclusion program will be as successful as the one implemented for the blood program.

Prevalence of the LAV/HTLV III by EIA in the Organ Donor Population

It is expected that prevalence of anti-LAV/HTLV III by EIA in the organs, and tissue donor population, may be four times higher than in the blood donor population.

It is estimated that 10% of the general population belongs to one of the high risk categories as defined by the Centre of Diseases Control. In the U.S. population, the prevalence of the antibody to LAV/HTLV III varies from 10% to 40% in the high risk groups.

It must be noted that this calculation is done on the basis of the prevalence of the antibody in the U.S. population. A lower prevalence in the Canadian population is expected. Furthermore, wide discrepancies of the prevalence of the antibody is anticipated from one area to another (higher prevalence in Toronto, Montreal and Vancouver than in Alberta).

Comment

It would be advisable for the Task Force to recommend immediate implementation of HTLV III testing (and hepatitis testing) before transplantation of any organs or tissues.

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